UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Lynn Vendinello, attest that I am the Director of the Communications Services and Information Division, Office of Program Support of the United States Environmental Protection Agency (EPA) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

1. **August 7, 2019, Letter Regarding EPA No Longer Approving Labeling, Including Prop 65 Warning (2 pages).**
2. **April 8, 2022, Letter from EPA Michal Freedhoff to CalEPA's Lauren Zeise Regarding Glyphosate (2 pages).**
3. **February 10, 2017, EPA Authorization for Deposition Testimony of EPA's Jess Rowland Regarding Roundup (4 pages).**
4. **April 20, 1998, EPA Memo Regarding Glyphosate Report of the Hazard Identification Assessment Review Committee (12 pages).**
5. **July 26, 1988, EPA Letter to Monsanto's Timothy Long Regarding Roundup (2 pages).**
6. **April 1, 1992, EPA Letter to Monsanto Regarding Roundup Advertising (1 page).**
7. **July 8, 2019, EPA Webpage: EPA Takes Next Step in Review Process for Herbicide Glyphosate, Reaffirms No Risk to Public Health (2 pages).**
8. **September 14, 2019, EPA Office of Pesticide Programs Label Review Manual (282 pages).**
9. **April 2019, EPA Glyphosate Proposed Interim Registration Review Decision Case Number 0178 (54 pages).**
10. **September 4, 2019, EPA Webpage: EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products (5 pages).**

Subscribed under the penalty of perjury on this 31st day of January, 2023.

Lynn Vendinello

Lynn Vendinello, Director
Communications Services and Information Division
Office of Program Support

CERTIFICATION OF TRUE COPY

I, Charlotte Youngblood, certify that I am the Acting Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

CHARLOTTE YOUNGBLOOD

Digitally signed by CHARLOTTE YOUNGBLOOD
Date: 2023.02.02 12:50:31 -05'00'

Charlotte Youngblood
Acting Associate General Counsel
General Law Office
Office of General Counsel

Date:_____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 7, 2019

Dear Registrant,

We are writing to you concerning label and labeling requirements for products that contain glyphosate.

On July 7, 2017, California listed glyphosate as a substance under Proposition 65[1], based on the International Agency for Research on Cancer's (IARC's) classification of the pesticide as "probably carcinogenic to humans." EPA disagrees with IARC's assessment of glyphosate. EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is "not likely to be carcinogenic to humans." EPA considered a more extensive dataset than IARC, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review. For more detailed information on this evaluation, please see the 2017 Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential[2]. Further, EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

On February 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction enjoining California from enforcing the state warning requirements involving the pesticide glyphosate's carcinogenicity, in part on the basis that the required warning statement is false or misleading[3].

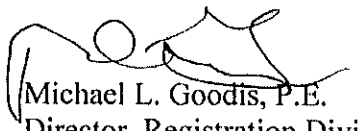
Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA. In registering pesticides, EPA must determine that the labeling complies with the requirements of FIFRA including that the product

[1] California's Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65) requires businesses to inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm. *See* California Office of Environmental Health Hazard Assessment, "Proposition 65," at https://oehha.ca.gov/proposition-65.
[2] https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073
[3] National Association of Wheat Growers, et al. v. Zeise, 309 F.Supp.3d 842 (E.D.Cal.)

not be misbranded. See FIFRA 3(c)(5)(B). Therefore, EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The warning statement must also be removed from all product labels where the only basis for the warning is glyphosate, and from any materials considered labeling under FIFRA for those products.

For any pesticide product that currently contains Proposition 65 warning language exclusively on the basis that it contains glyphosate, EPA requests the submission of draft amended labeling that removes such language within ninety (90) days of the date of this letter.

Sincerely,



Michael L. Goodis, P.E.
Director, Registration Division
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 8, 2022

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Lauren Zeise
Director
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street
Sacramento, California 95814

Dear Dr. Zeise:

Thank you for your letter of March 21, 2022, to the U.S. Environmental Protection Agency (EPA) regarding glyphosate and California's Safe Drinking Water and Toxics Enforcement Act of 1986, also known as Proposition 65.

Your letter proposes a revision to previously proposed safe harbor language that businesses could use to satisfy California's notification requirements for certain glyphosate products under Proposition 65. It further requested that EPA provide input on whether the newly proposed language could be approved, if requested by a pesticide registrant, for inclusion on pesticide labels for products containing glyphosate as an active ingredient and sold in California. As explained below, EPA could approve the newly proposed language.

The Agency continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate. Furthermore, EPA's conclusion remains consistent with many international expert panels and regulatory authorities (https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073).

Nonetheless, EPA recognizes that the revised safe harbor language proposed by the Office of Environmental Health Hazard Assessment (OEHHA) acknowledges the EPA position: CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The letter from OEHHA further requests that EPA clarify its position as previously stated in its August 7, 2019, letter to registrants regarding products that contain glyphosate. That 2019 letter focused on the application of the default Proposition 65 safe harbor warning language to products containing glyphosate and advised that EPA would no longer approve glyphosate labeling containing that statement because it was in conflict with the Agency's scientific conclusions regarding glyphosate. The Agency concluded that the standard warning language for products containing glyphosate was false or misleading and therefore, any glyphosate products bearing the statement would be considered misbranded.

While EPA's scientific conclusions regarding the glyphosate cancer classification have not changed since the August 7, 2019, letter to glyphosate registrants, it has determined that the new glyphosate-specific safe harbor language proposed in OEHHA's recent letter is sufficiently clear regarding EPA's position and thus would not be considered false and misleading. Therefore, this revised language could be approved by EPA if pesticide registrants requested it for inclusion on glyphosate product labels, and the products would not be considered misbranded. As stated in OEHHA's letter, EPA notes that inclusion on the product label is one of several methods that companies can use to satisfy California's notification requirements under Proposition 65.

EPA appreciates the constructive approach that California is pursuing to address this matter and looks forward to further strengthening our relationships with our stakeholders as we forge ahead together in our work. We thank you for taking the time to write on this important matter.

Sincerely,

MICHAL FREEDHOFF

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Date: 2022.04.08 13:26:16 -04'00'

Michal Freedhoff, Ph.D.
Assistant Administrator

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

AUTHORIZATION AND INSTRUCTIONS FOR THE DEPOSITION TESTIMONY OF RETIRED U.S. ENVIRONMENTAL PROTECTIONS AGENCY EMPLOYEE, JESS ROWLAND

SUBPOENAED EMPLOYEE
Mr. Jess Rowland
Retired Deputy Division Director

DATE OF REQUEST
February 10, 2017

EXHIBIT 11-1
WIT: Rowland
DATE: 4-24-17
C. Campbell, RDR CRR CSR #13921

CASE
In Re: Roundup Products Liability Litigation

COURT & DOCKET NUMBER
U.S. Dist. Court, N. Dist. Cal.
MDL No. 2741, Case No. 3:16-md-02741-VC

REQUESTING PARTY
Plaintiff

DATE OF DEPOSITION
April 26, 2017

DESCRIPTION OF CIRCUMSTANCES/TESTIMONY:

Plaintiffs in the above-referenced litigation, to which the U.S. Environmental Protection Agency (EPA or Agency) is not a party, seek deposition testimony from you, Mr. Jess Rowland, retired Deputy Division Director in the Agency's Health Effects Division, Office of Pesticides Programs (OPP) and former co-chair of the Agency's Cancer Assessment Review Committee (CARC).

The requested testimony relates to your work with the Agency's Pesticide Registration Review program, which reviews all registered pesticides at least every 15 years, as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act. While you were an Agency employee, EPA was conducting a registration review of glyphosate to ensure that it continues to satisfy the statutory standard for registration; that is, the pesticide generally will not cause unreasonable adverse effects on the environment, including a determination that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

This letter authorizes you to testify about four specific topics (listed below) that relate to the Agency's glyphosate review and information that you acquired in the scope and performance of your official EPA duties. This letter also provides instructions and limitations that you are to follow while responding to deposition questions related to information that you acquired as an EPA employee in the scope and performance of your official EPA duties.

AUTHORITY:

A subpoena for testimony was directed to Mr. Rowland, a retired Agency employee. In litigation to which EPA is not a party, former employees may not provide testimony concerning information acquired in the course of performing official Agency duties nor because of their previous employment status with the Agency, unless authorized to do so by the General Counsel or his designee. 40 C.F.R. §2.401.

These regulations have the force and effect of federal law. *Ex Parte Sackett,* 74 F.2d 922, 923 (9th Cir. 1935). Such regulations are promulgated pursuant to the authority granted by the Federal Housekeeping Statute, 5 U.S.C. § 301. To the extent such a regulation is a valid exercise of legislative authority, as embodied in a legislative regulation, it is given the force and effect of federal law, and a court may not premise a finding of contempt by a former Agency employee for his adherence to that law. The U.S. Supreme Court has specifically recognized the authority of a federal agency to restrict the testimony of its subordinate employees. *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951); *Boske v. Comminfore*, 177 U.S. 459 (1900); *see also, Houston Business Journal, Inc. v. Office of the Comptroller of the Currency, Department of Treasury*, 86 F.3d 1208, 1212 (D.C. Cir. 1996); *Edwards v. Department of Justice*, 43 F.3d 312,316 (7th Cir. 1994); *Boron Oil Co. V Downie*, 873 F.2d 67, 69-70 (4th Cir. 1986); *Reynolds Metals Company v. Crowther*, 572 F. Supp. 288, 290 (D. Mass. 1982).

INSTRUCTIONS:

In accordance with the Agency's regulation, 40 C.F.R. § 2.401-2.406, you are hereby authorized to testify about the topics and to the extent stated herein.

Authorized Testimony Topics:

1. For the time period of May 1, 2014 to Mr. Rowland's retirement from EPA: Mr. Rowland's duties and role on Cancer Assessment Review Committee (CARC) where such duties and role regard communications about glyphosate or glyphosate-based formulations that Mr. Rowland may have had with Monsanto's employees, ex-employees, lobbyists, contractors or agents, whether written or verbal.

2. For the time period of May 1, 2014 to Mr. Rowland's retirement from EPA: Mr. Rowland's written or verbal communications with managers or staff at the Agency for Toxic Substances and Disease Registry or the National Toxicology Program concerning the CARC's cancer risk assessment of glyphosate or glyphosate-

based formulations.

3. For the time period of May 1, 2014 to Mr. Rowland's retirement from EPA: Mr. Rowland's written or verbal communications with the Working Group of experts or staff who worked on the International Agency for Research on Cancer's (IARC) Monographs on glyphosate.

4. For the time period of May 1, 2014 to Mr. Rowland's retirement from EPA: Mr. Rowland's involvement with the creation of the CARC glyphosate memo on carcinogenicity dated October 1, 2015 and Mr. Rowland's involvement in the "inadvertent release" and subsequent retraction of that report in or around April and May 2016.

You are instructed to not give any testimony which would constitute opinion or expert testimony based upon information which you acquired in the scope and performance of your official EPA duties.

You are instructed to not give any testimony that is protected by the deliberative process privilege. The deliberative process privilege applies to and protects from disclosure any communications or information acquired in the scope and performance of your official EPA duties that remained internal to EPA or the Executive Branch and that contain predecisional deliberations, predecisional opinions or predecisional recommendations. Predecisional information is created in the activities leading up to an Agency decision-making processes and reflect the flow of opinions, recommendations or advice.

You are instructed to not give any testimony protected by the attorney-client privilege. The attorney-client privilege applies to and protects from disclosure any legal advice, acquired in the scope and performance of your official EPA duties, that you received from an attorney in the Agency's Office of General Counsel.

This authorization and the related instructions apply to all forms of information, including both oral and written testimony and to requests for any Agency records. Under no circumstance (including the invocation of a contempt citation by the court) are you to provide any information acquired in the scope and performance of your official EPA duties that is outside the scope of these instructions.

The Agency takes no position on your testimony related to activities that occurred after your retirement from the Agency so long as those post-employment activities do not contain EPA equities or information acquired in scope and performance of your official EPA duties.

To the extent that any party seeks disclosure of information which you acquired in the scope and performance of your official EPA duties that is beyond the scope of this authorization, you are instructed to decline to answer on the basis that the information requested is outside the scope of the authority granted to you by EPA. If you are ordered by the court to provide the information sought, you are to respectfully decline to do so upon the same grounds and

refer the court to this authorization and to request that the court grant a stay of the proceedings to allow for representation by the Office of United States Attorney.

If any questions or issues related to this authorization arise, you should contact the Agency's Office of General Counsel at 202-564-4845.

Sincerely,

Date: March 30, 2017

Wendy Blake
Associate General Counsel
General Law Office

cc: Messrs. Jon Jacobs, Andrew Steward and Nicholas Liao, Mr. Rowland's Personal Counsel.
Messrs. Michael J. Miller and Timothy Litzenburg, Plaintiffs' Counsel.
Wendy Cleland-Hamnett, Acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.
Rick P. Keigwin, Jr., Acting Director, Office of Pesticides Programs, OCSPP.
Dana Vogel, Director, Health Effects Division, OPP, OCSPP.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DATE: April 20, 1998

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: ***GLYPHOSATE*** - Report of the Hazard Identification Assessment Review Committee.

FROM: William Dykstra, Toxicologist. William Dykstra 4/20/98
Registration Action Branch 1
Health Effects Division (7509C)
and
Jess Rowland, Executive Secretary 4/20/98
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)

THROUGH: K. Clark Swentzel, Chairman, K. Clark Swentzel 4/21/98
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)
and
Mike Metzger, Co-Chairman
Hazard Identification Assessment Review Committee 4/21/98
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist
Registration Action Branch 1
Health Effects Division (7509C)

PC Code: 417300

On March 26, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee evaluated the toxicology data base of **GLYPHOSATE,** re-assessed the Reference Dose (RfD) established in 1992 as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to glyphosate as required by the Food Quality Protection Act (FQPA) of 1996. The Committee's conclusions are presented in this report.

Committee Members in Attendance

Members present were: Mike Metzger (Co-Chairman), Clark Swentzel (Chairman), Bill Burnam, Sue Makris, Melba Morrow, Karen Hammernik, Karl Baetcke, Robert Fricke, John Redden, and Jess Rowland (Executive Secretary) . Member(s) in absentia: None. Data was presented by William Dykstra of the Registration Action Branch 1.

In attendance was also Julianna Cruz of Registration Action Branch 1.

Data Presentation:
and
Report Presentation

William Dykstra.
Toxicologist

Report Concurrence:

Jess Rowland
Executive Secretary

I. INTRODUCTION

On March 26, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee evaluated the toxicology data base of Glyphosate, re-assessed the Reference Dose (RfD) established in 1992 as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to glyphosate as required by the Food Quality Protection Act (FQPA) of 1996.

II. HAZARD IDENTIFICATION

A. Acute Reference Dose (RfD)

Study Selected: None §

MRID No.: None

Executive Summary:

Dose and Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: A review of the rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glyphosate lacks a leaving group. Therefore, it would not seem likely to inhibit esterases, which is the presumptive neurotoxic mechanism of concern for all organophosphates.

Uncertainty Factor (UF): None

This Risk Assessment is **NOT** required.

B. Chronic RfD

Study Selected: Rabbit Developmental study § 83-3(b)

MRID No.: 00046363

Executive Summary: Groups of 16/dose Dutch Belted rabbits were dosed with technical glyphosate at doses of 0, 75, 175, or 350 mg/kg/day between gestation days 6 to 27. Maternal effects were seen at only the high dose and consisted of diarrhea, nasal discharge and death [10/16]. Developmental effects were not seen at any dose tested. Therefore, the NOEL and LOEL for maternal toxicity were 175 mg/kg/day and 350 mg/kg/day, respectively.

Dose and Endpoint for Establishing RfD: NOEL = 175 mg/kg/day based on death, diarrhea, and nasal discharge at 350 mg/kg/day (LOEL).

Uncertainty Factor(s): 100 (10 x for interspecies extrapolation and 10 x for intraspecies variation).

$$\textbf{Chronic RfD} = \frac{\text{175 mg/kg/day (NOEL)}}{\text{100 (UF)}} = \textbf{2.0 mg/kg/day}$$

Comments about Study/Endpoint/Uncertainty Factor: The NOEL for maternal toxicity in the rabbit developmental study was the lowest NOEL of all the major studies which include the 24-month mouse carcinogenicity study [NOEL = 750 mg/kg/day], the 1-year dog study [NOEL = 500 mg/kg/day], 2-year chronic/onco rat study [NOEL = 400 mg/kg/day], 2-generation rat reproduction study [NOEL = 500 mg/kg/day] and rat developmental study [NOEL = 1000 mg/kg/day]

This risk assessment is required.

C. Occupational/Residential Exposure

1. Dermal Absorption

Dermal Absorption Factor: A dermal absorption factor is not applicable since dermal risk assessments are not required.

2. Short-Term Dermal - (1-7 days)

Study Selected: None §

MRID No.: None

Executive Summary: None

Dose and Endpoint for Risk Assessment: Not Applicable.

Comments about Study/Endpoint: No systemic or dermal toxicity was seen following repeated dermal applications of technical glyphosate at 0, 100, 1000 or 5000 mg/kg/day, 6 hours/day, 5 days/week for three consecutive weeks to male and female New Zealand rabbits. The NOEL was 1000 mg/kg/day and the LOEL was 5000 mg/kg/day based on decreased food consumption in females [MRID No. 00098460]. In addition, the use of a 3% dermal absorption rate (estimated) in conjunction with the oral NOEL of 175 mg/kg/day established in the rabbit developmental study yields a dermal equivalent dose of > 5000 mg/kg/day.

This risk assessment is **NOT** required.

3. Intermediate-Term Dermal (7 Days to Several Months)

Study Selected: None

MRID No.: None

Executive Summary: None

Dose/Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: See short term

This risk assessment is **NOT** required.

4. Long-Term Dermal (Several Months to Life-Time)

Study Selected: None

MRID No.: None

Executive Summary: None

Dose and Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint:. See short term

This risk assessment is **NOT** required.

5. Inhalation Exposure (Any Time period).

Study Selected: None

MRID No.: None

Executive Summary: None

Dose/Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: Based on the low toxicity of the formulation products (Toxicity Category III or IV) and the physical characteristics of the technical product (wetcake) there is minimal concern for potential inhalation exposure or risk. The acute inhalation study was waived for technical glyphosate.

This risk assessment is **NOT** required.

D. Recommendation for Aggregate Exposure Risk Assessments

There are no registered residential uses at the present time. Therefore, aggregate exposure risk assessments will be limited to food + water.

III. CLASSIFICATION OF CARCINOGENIC POTENTIAL

1. Combined Chronic Toxicity/Carcinogenicity Study in Rats

Executive Summary : Randomized groups of 60/sex/dose Sprague-Dawley rats were fed glyphosate at dietary levels of 0, 2000, 8000, or 20,000 ppm [male: 0, 89, 362, or 940 mg/kg/day; female: 0, 113, 457, or 1183 mg/kg/day]. The NOEL was 8000 ppm [362 mg/kg/day for males and 457 mg/kg/day for females] and the LOEL was 20,000 ppm [940 mg/kg/day for males and 1183 mg/kg/day for females] based on decreased weight gain in females, decreased urinary pH in males, increased incidence of cataracts and lens abnormalities in males, and increased absolute and relative liver weight in males. The carcinogenic potential was negative.

MRID No. 41643801

Discussion of Tumor Data: The study showed a slightly increased incidence of pancreatic islet cell adenomas in the low and high dose males; hepatocellular adenomas in the low and high dose males; and thyroid C-cell adenomas in the mid and high dose males and females. The Agency concluded that these adenomas were not treatment-related and glyphosate was not considered to be carcinogenic in this study. The pancreatic islet cell adenomas did not display a positive dose-trend in their occurrence; there was no progression to carcinoma and the incidence of pancreatic hyperplasia was not dose-related. The hepatocellular adenomas were not statistically significant by pair-wise comparison; the incidence was within the range of historical controls; there was no progression to carcinoma and the hyperplasia was not compound-related. The C-cell adenomas were statistically significant by pair-wise comparison and were not dose-related; there was no progression to carcinoma and there was no significant dose-related increase in severity or incidence of hyperplasia in either sex.

Adequacy of the Dose Levels Tested: The highest dose tested was the limit dose of 20,000 ppm in both sexes.

2. Carcinogenicity Study in Mice

Executive Summary: Randomized groups of 50/sex/dose CD-1 mice were fed glyphosate in the diet for 2 years at doses of 0, 1000, 5000, or 30,000 ppm [0, 150, 750, or 4500 mg/kg/day]. The systemic NOEL was 5000 ppm and the LOEL was 30,000 ppm based on decreased weight gain in both sexes, hepatocyte necrosis and interstitial nephritis in males and increased incidence of proximal tubule epithelial basophilia and hypertrophy in females. The carcinogenic potential was negative.

MRID No. 00130406, 00150564

Discussion of Tumor Data The incidence in males of renal tubular adenomas, a rare tumor, was 1, 0, 1, and 3 in the control, low, mid, and high dose groups, respectively. Although the trend was significant, there was no statistical significance by pairwise comparison of the control and high dose group. The incidence at the high dose exceeded the occurrence of historical controls from the testing laboratory. The non-neoplastic findings in the male kidney did not occur in a increased dose-related manner and the tumorigenic findings in the kidney were considered to occur by chance rather than as a result of treatment.

Adequacy of the Dose Levels Tested: The highest dose tested [30,000 ppm] exceeded the limit dose of 7000 ppm for both sexes of mice.

3. Classification of Carcinogenic Potential The OPP Cancer Peer Review Committee classified glyphosate as a "Group E " pesticide [no evidence for carcinogenicity in two acceptable species].

IV. FQPA CONSIDERATIONS

1. Neurotoxicity:

There were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glyphosate lacks a leaving group. Therefore, it would not seem likely to inhibit esterases, which is the presumptive neurotoxic mechanism of concern for all organophosphates.

2 Developmental Toxicity

In a prenatal developmental toxicity study , pregnant Sprague-Dawley rats received oral administration of glyphosate (98.7%) in 0.5% aqueous methocel at 0, 300, 1000 or 3500 mg/kg/day during gestation days 6 through 19. For maternal toxicity, the NOEL was 1000 mg/kg/day and the LOEL was 3500 mg/kg/day based on diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and inviable fetuses/dam, and death (24% of the group). For developmental toxicity, the NOEL was 1000 mg/kg/day and the LOEL was 3500 mg/kg/day based on increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights (MRID # 00046362).

In a prenatal developmental toxicity study, pregnant New Zealand white rabbits received oral administration of glyphosate (98.7%) in 0.5% aqueous methocel at 0, 75, 175 or 350 mg/kg/day during gestation days 6 through 27. For maternal toxicity, the NOEL was 175 mg/kg/day and the LOEL was 350 mg/kg/day based on diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). Developmental toxicity was not observed at any dose tested. For developmental toxicity, the NOEL was ≥ 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity) (MRID # 00046363).

3. Reproduction Toxicity

In a three-generation reproduction study, Sprague-Dawley rats received diets containing glyphosate at 0, 3, 10 or 30 mg/kg/day for three generations. For parental systemic toxicity, the NOEL was 30 mg/kg/day (highest dose tested). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F_{2b} pups. However, this effect (focal tubular dilation of the kidneys) was not observed at the 1500 mg/kg/day level in a 2-generation rat reproduction study discussed below. Therefore, the OPP Developmental Peer Review Committee concluded that the effect seen in the three generation study was a spurious rather than glyphosate-related effect. No reproductive or offspring toxicity was observed; NOELs was ≥30 mg/kg/day (MRID # 00105995).

In a two-generation reproduction study, Sprague-Dawley rats received diets containing glyphosate at 0, 2000, 10,000 or 30,000 ppm for two generations. Treatment-related effects observed at 30,000 ppm included soft stools, very frequent, in the F_0 and F_1 males and females, decreased food consumption and body weight gain of the F_0 and F_1 males and females during the growth (premating) period, and decreased body weight gain of the F_{1a}, F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the 3-generation study, was not observed at any dose level in this study. Based on the above findings, the parental and developmental (pup) NOEL's are 500 mg/kg/day and the parental and developmental (pup) LOEL's are 1500 mg/kg/day. The reproductive toxicity NOEL is ≥1500 mg/kg/day (MRID # 41621501).

4. Additional information from the literature. No studies were available

5. Determination of Susceptibility

The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to glyphosate. In the prenatal developmental toxicity study in rats, developmental toxicity was seen in the presence of maternal toxicity at the highest dose tested. No developmental toxicity was seen in the rabbits. In reproductions toxicity studies, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

6. Recommendation for a Developmental Neurotoxicity Study

i. Evidence that suggest requiring a developmental neurotoxicity study:

There was no evidence to suggest that a developmental neurotoxicity study was needed.

ii. Evidence that do not support a need for a developmental neurotoxicity study: Rat and rabbit developmental studies and 2-generation rat reproduction study.

7. Determination of the FQPA Safety Factor:

The application of an FQPA factor for the protection of infants and children from exposure to glyphosate required by FQPA, will be determined during risk characterization by the FQPA Safety Committee. However, the HIARC, based on hazard assessment, recommends to the FQPA Safety Factor Committee that the additional 10 x factor should be removed because:

(i) The data provided no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to glyphosate.

(ii) No evidence of developmental anomalies, including abnormalities in the development of fetal nervous system was observed in the pre-and/or postnatal studies.

(iii) The toxicology data base is complete and there are no data gaps.

V. DATA GAPS none

012586

VI SUMMARY OF TOXICOLOGY ENDPOINT SELECTION

The doses and toxicological endpoints selected for various exposure scenarios are summarized below.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	None	No toxicological endpoint attributable to a single dose was identified in oral studies including the rat and rabbit developmental toxicity studies.	
	Acute RfD = None		
Chronic Dietary	NOEL = 175 UF = 100	Mortality, diarrhea, and nasal discharge	Developmental - Rabbit
		Chronic RfD = 2.0 mg/kg/day	
Short-, Intermediate and Long-Term (Dermal)	None	No systemic toxic effects seen at doses up to 1000 mg/kg/day in the 21 day dermal toxicity study. Risk assessment is not required.	
Inhalation (Any Time Period)	None	Based on low toxicity of formulations and technical material [wet cake] inhalation study was waived. Risk assessment is not required.	

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Chemical:	**Glyphosate**
PC Code:	***417300***
HED File Code	**21100 HIARC**
Memo Date:	***04/20/98***
File ID:	**TX012586**
Accession Number:	**412-02-0011**

HED Records Reference Center
03/01/2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 26 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. Timothy Long
Roundup Registration Manager
Monsanto Corporation
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

Dear Dr. Long:

On June 8, 1988, a member of the medical school faculty at the University of Iowa, Iowa City, informed the EPA that there were television advertisements for Roundup, showing the chemical being applied from a "bean bar". The applicators were wearing gym shoes, short sleeve shirts and long pants. The caller was concerned about safety to the applicators using Roundup as depicted in the ad. We have viewed a tape of this advertisement.

In the Glyphosate Registration Standard issued by the Agency in June, 1986, the Agency concluded that "formulations of glyphosate for agricultural use cause moderate eye irritation and some skin irritation." The following worker safety language was required to appear on all end-use products containing glyphosate (except for those labeled for homeowner use only) in order to reduce worker exposure to formulations of Glyphosate, such as Roundup:

Worker Safety Rules

THIS PRODUCTS CAUSES EYE IRRITATION AND SKIN IRRITATION...

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, CLEANING, DISPOSAL OF THE PESTICIDE SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS BEFORE THE SPRAY HAS DRIED.

Wear goggles or a face shield, chemical-resistant gloves and chemical-resistant shoes, shoe covers or boots...

These label changes were to have appeared on all products in channels of trade by June 30, 1988.

In a May 1988 letter to you, the Agency stated that it would defer the label requirements for Worker Safety Rules for eye and skin protection until a planned PR notice on personal protective equipment had gone into effect. The Agency also stated that "we feel that you should begin a investigation of the high number of eye and/or skin injuries associated with glyphosate use in California."

At no time, however, were the label requirements modified or waived. This deferral does not imply that it is safe to use products containing glyphosate without protective equipment. The California Department of Food and Agriculture reported that glyphosate ranked third in the number of illnesses reported from exposure to pesticides. The majority of these illness were skin and eye irritations occurring during mixing, loading and application of glyphosate.

We are concerned that advertisements for Roundup (running through July in Iowa and perhaps other soybean growing areas) show the product being applied in a manner inconsistent with protective clothing requirements. In addition to our specific concerns with the safe use of Roundup, we believe that any advertisement for a pesticide should depict usage that minimizes unnecessary skin and eye exposure.

We feel that these advertisements are inappropriate, and we request that you cease running these spots, or that they be suitably modified. Please look into this matter immediately and contact us.

Sincerely,

E J Tinsworth

Edwin Tinsworth, Director
Registration Division
Office of Pesticides Programs

cc: David McLaughlin C2NC
Advertising Manager for Roundup
Monsanto

P1.3024.3

APR 07 1992

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION VII
726 MINNESOTA AVENUE
KANSAS CITY, KANSAS 66101

APR 01 1992

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Monsanto Co., Agricultural Products
Mail Zone C2NJ
800 N. Lindbergh
St. Louis, Missouri 63166

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, we have reviewed copies of advertising literature pertaining to your distribution of the pesticide product ROUNDUP.

This literature makes claims considered misleading regarding the aforementioned product, such as, "Roundup doesn't stay in the soil, won't leach to nearby plants and breaks down into natural substances...Nothing kills weeds better, or easier, than Roundup...Easy-to-use...Biodegradable." Statements such as these were never accepted in connection with the registration of the product. Use of these statements in connection with the marketing of the product would constitute a violation of the FIFRA. Therefore, such statements should be removed from all literature advertising the product or data submitted to support them.

We are requesting that you review all pesticide advertising literature for misleading claims. We are also requesting that you cease distribution of ROUNDUP advertising material until all misleading claims have been deleted, and that you send us copies of the revised advertising material within thirty (30) days from receipt of this letter.

This letter does not preclude us from taking enforcement action in this matter.

You may contact Pamela Johnson, of my staff, at (913) 551-7480 if you have any questions regarding this letter.

Sincerely,

Leo J. Alderman, Chief
Toxics and Pesticides Branch
Air and Toxics Division

RECYCLE

EPA United States Environmental Protection Agency

EPA Takes Next Step in Review Process for Herbicide Glyphosate, Reaffirms No Risk to Public Health

For Release: April 30, 2019

Updated: July 8, 2019

Today, the U.S. Environmental Protection Agency (EPA) is taking an important step in the agency's review of glyphosate. As part of this action, EPA continues to find that there are no risks to public health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen. The agency's scientific findings on human health risk are consistent with the conclusions of science reviews by many other countries and other federal agencies. While the agency did not identify public health risks in the 2017 human health risk assessment, the 2017 ecological assessment did identify ecological risks. To address these risks, EPA is proposing management measures to help farmers target pesticide sprays on the intended pest, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate.

"EPA has found no risks to public health from the current registered uses of glyphosate," said **EPA Administrator Andrew Wheeler**. "Today's proposed action includes new management measures that will help farmers use glyphosate in the most

effective and efficient way possible, including pollinator protections. We look forward to input from farmers and other stakeholders to ensure that the draft management measures are workable, realistic, and effective."

"If we are going to feed 10 billion people by 2050, we are going to need all the tools at our disposal, which includes the use the glyphosate," **U.S. Secretary of Agriculture Sonny Perdue** said. "USDA applauds EPA's proposed registration decision as it is science-based and consistent with the findings of other regulatory authorities that glyphosate does not pose a carcinogenic hazard to humans."

Glyphosate is the most widely used herbicide in U.S. agriculture and has been studied for decades. Glyphosate is used on more than 100 food crops, including glyphosate-resistant corn, soybean, cotton, canola and sugar beet. Non-agricultural uses include residential areas, aquatic areas, forests, rights of way, ornamentals and turf.

Once the Federal Register notice publishes, the public will be able to submit comments on EPA's proposed decision at www.regulations.gov in docket # EPA-HQ-OPP-2009-0361. Public comments will be due on or before Sept. 3, 2019. EPA's responses to the comments received on the draft ecological and human health risk assessments and the benefits assessment will be in the docket.

Find more information about glyphosate, including today's proposed interim decision and supporting documents.

See the glyphosate draft risk assessments and supporting documents.

LAST UPDATED ON JULY 12, 2019

Office of Pesticide Programs

Label Review Manual

http://commons.wikimedia.org, photo by "Daderot"

Label Review Manual

Chapters List

Title	Revision Date
Chapter 1: Purpose of the Manual	December 2016
Chapter 2: What is a Pesticide?	April 2014
Chapter 3: General Labeling Requirements NEW	March 2018
Chapter 4: Types of Label Reviews	December 2011
Chapter 5: Ingredient Statement	May 2012
Chapter 6: Use Classification	January 2012
Chapter 7: Precautionary Statements NEW	March 2018
Chapter 8: Environmental Hazards	September 2012
Chapter 9: Physical or Chemical Hazards	September 2012
Chapter 10: Worker Protection Labeling	February 2016
Chapter 11: Directions for Use	December 2014
Chapter 12: Labeling Claims	November 2013
Chapter 13: Storage and Disposal	July 2013
Chapter 14: Identification Numbers	November 2012
Chapter 15: Company Name and Address	August 2017
Chapter 16: Graphics and Symbols	August 2017
Chapter 17: Net Contents/Net Weight NEW	February 2018
Chapter 18: Unique Product Labeling	September 2013

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Chapter 5: Ingredient Statement

Chapter 6: Use Classification

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Chapter 8: Environmental Hazards

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Chapter 18: Unique Product Labeling

Revised December 2016

Label Review Manual

Chapter 1: Purpose of the Manual

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What's changed in this version?

- Reinstate presentation of the Label Review Manual in its entirety (Chapters 1-18).

I. Purpose

This Label Review Manual (LRM or Manual) provides guidance on pesticide labeling with the goal of improving the quality and consistency of pesticide labels. Historically, the LRM was developed as a training tool for EPA staff in the Office of Pesticide Programs (OPP). However, over time, its audience has grown from OPP label reviewers to include other federal agencies as well as external parties such as state, local, and tribal agencies, pesticide registrants, and other individuals who work with pesticide labeling.

II. Background

Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides. Unlike other types of product labels, pesticide labels are enforceable and must include the statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." 40 CFR 156.10(i)(2)(ii). In other words, ***the label is the law***.

A critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used. Therefore, the accuracy of a label is vital as it can impact:

- EPA and other agencies that use the label to manage and mitigate pesticide risks.
- EPA and other agencies that enforce pesticide production, distribution, and use.
- Registrants, including pesticide manufacturers, and their supplemental distributors.
- Pesticide applicators who rely on the label for hazard and safety information and use directions.
- Bystanders and other individuals who may be exposed to the pesticide.

III. Considerations

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and its implementing regulations under Title 40, Chapter I, Subchapter E in the Code of Federal Regulations (CFR) govern pesticide registration and labeling requirements. FIFRA and its implementing regulations govern what **must** be included on pesticide labels.

Other EPA documents such as Pesticide Registration Notices (PR Notices or PRN) and this Manual provide guidance on what **should** be included on pesticide labels.

Additional labeling information based on chemical- and/or product-specific information must also be considered. These include product chemistry and acute toxicity reviews on the product's formulation, science reviews on an active or inert ingredient and its registered use(s), Reregistration Eligibility Decisions, and Registration Review Decisions.

It is important to note that **this Manual does not establish new requirements, policies, or guidance;** instead, it summarizes current requirements, policies, and guidance that are found in published regulations, publicly available documents, and historically established practices. It also provides clarification and examples of labeling requirements and includes hyperlinks to source references. It is meant as a guide to understanding the various parts of a pesticide label.

Instructions directed toward EPA staff and label reviewers will be marked accordingly, using a symbol where possible.

IV. Format

This Manual is organized by individual chapters focusing on specific label topics. It is designed as a living document that can be updated as needed to reflect current policies or changes to existing laws or regulations.

The LRM is available in its entirety as well as individual chapters on EPA's pesticides webpage.

V. Maintenance

The Label Review Manual Subcommittee (LRMS), under the Labeling Consistency Committee (LCC), maintains and updates the LRM regularly. An announcement will be made on the EPA's pesticides webpage if and when revised chapters become available.

The "Revised [Date]" at the top of each chapter's cover page indicates when the individual chapter was revised.

The *What's changed in this version?* section summarizes significant changes to each chapter since its last revision.

VI. Change requests

LRM change requests may be submitted by anyone, including OPP and other EPA staff, other federal, state, local, and tribal agencies, pesticide registrants, researchers, and private citizens. All requests will be reviewed by the LRMS and/or the LCC before a decision is made.

Notify the LCC of any OPP policy changes that affect generic pesticide labeling and would be appropriate for inclusion in the LRM.

Internal EPA staff can submit requests by:

- Emailing the LRMS or the LCC directly via its chairs or your division's representatives.
- Filling out the Labeling Consistency Question Form online.

External parties can submit requests by:

- Filling out the Labeling Consistency Question Form online.

Revised April 2014

Label Review Manual

Chapter 2: What Is a Pesticide?

National Garden Bureau

I. Introduction

This chapter discusses the statutory and regulatory criteria used to determine whether or not a product is a pesticide requiring registration under FIFRA. Relevant FIFRA definitions are found in section 2 of the statute and the applicable regulations are at *40 CFR Part 152, Subparts A and B*. Label reviewers should use the statute and regulations when evaluating the "pesticide" status of products or potential products. It is acceptable to discuss whether hypothetical products are pesticides with anyone, including state enforcement personnel, registrants, applicants or the general public. Whether or not a particular product that is the subject of an application is a pesticide under FIFRA must be treated confidentially through applicable CBI protections. A final decision about the pesticide status of a particular product must be made in witing to the applicant or registrant and should be in response to a written request for an Agency determination, which includes proposed labeling and the composition of the product.

As discussed in detail below, there are a number of types of products that the Agency has determined are not pesticides and others that the Agency has exempted from regulation even though they are pesticides. If a label reviewer determines that a product is a pesticide, the label reviewer should consider whether the pesticide has been exempted from the FIFRA registration requirements.

If the label reviewer determines that the product is not a pesticide, the label reviewer must consider whether the product is a device. The last section of this chapter addresses this topic.

II. Products that are *not* pesticides

Some substances and products may be excluded from FIFRA registration if they meet certain conditions or criteria. *40 CFR 152.6* sets out the following types of products that fall into this category.

A. Liquid Chemical Sterilants

A liquid chemical sterilant product is not a pesticide under *section 2(u) of FIFRA* if it meets all of the following criteria. See *40 CFR 152.6(a)*. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

1. **Composition.** The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded from regulation under FIFRA. Ethylene oxide products are not liquid products and are therefore not excluded by this provision.

2. **Claims.** The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than "sterilant" are not excluded and are jointly regulated by EPA and FDA.

3. **Use site**

   - The product must be intended and labeled only for use on critical or semi-critical devices. A "critical device" is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A semi-critical device is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.
   - Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA, and must be registered by EPA.
   - Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.
   - Liquid chemical sterilants intended to treat aseptic food packaging systems are also not excluded from FIFRA; these products are subject to registration by EPA as pesticides as well as approval by FDA as food additives.

B. Nitrogen Stabilizers

A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria found in *40 CFR 152.6(b)*:

1. The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of *40 CFR 152.6* living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

2. The substance was in "commercial agronomic use" in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

3. The substance was not registered under FIFRA before January 1, 1992.

4. Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. See *40 CFR 152.6(b)(4) and (5)* to learn what EPA considers to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production and for further information on this topic.

C. Products Labeled Only for Use in or on Living Man or Animals

Products excluded are those meeting one of the following criteria:

1. Products intended for use for the control of fungi, bacteria, viruses, or other microorganisms in or on living humans or animals, and labeled accordingly. See *40 CFR 152.6(c) and (d)*. Such products include, for example: Athlete's foot remedies, dandruff medications, aquaculture and aquarium additives for treatment of fish diseases, and dermal disinfectants. Note: These exceptions apply only to antimicrobials (fungicides, disinfectants, viricides, etc.). Insecticides (pesticides that kill insects as opposed to microbes) are not included in the "living body" exception. Thus, products such as mosquito repellents, flea and tick remedies for pets, and other insecticides) used directly on the living body of humans, pets, and livestock have historically been considered to be pesticides and are required to be registered. Note that contact lens solutions that disinfect the lens in the contact lens holder are exempt from federal registration under FIFRA through an agreement with the Food and Drug Administration. An animal feed containing an animal drug is not a pesticide under *section 2(u) of FIFRA*. See also *40 CFR 152.6(e)*. An animal feed containing an animal drug is subject to regulation by the FDA under the FFDCA.

2. Products intended for use for control of internal invertebrate parasites or nematodes in living humans or animals, and labeled accordingly. See *40 CFR 152.5(b)*.

D. Products Intended Only to Aid in the Growth of Desirable Plants

As an initial matter, it is important to note that there is an important distinction between *plant nutrients*, which may be exempt from registration, and *plant regulators*, which require registration (and are defined in *FIFRA at 2(v)*), and in Section III. D. of this chapter. Plant nutrients are described below.

Examples of products that aid in the growth of desirable plants, types of which are found in *40 CFR 152.6(g)*, include:

1. **Plant or leaf coatings** designed to protect against frost or to retard water loss through transpiration. These types of products are usually glycerol-based. Similar products are sometimes sold as cut-flower preservatives. As long as plant disease or plant regulator claims are not made for the product and its composition is not such that pesticide benefits would be delivered, registration has historically not been required.

2. **Products sold as vase water additives for cut flowers**, although such products bear special scrutiny. If they are composed, as many are, of simple sugars intended to supply nourishment to the cut flower, they are likely not under the purview of FIFRA. Historically, however, products with claims to prevent bacterial or fungal growth in the vase water, claims such as "delays flower opening", claims to control stem rot or decay or products with chemicals that only have pesticidal uses have been subject to FIFRA registration.

3. **Food washing products** that do not claim to remove bacteria such as *e-coli* or salmonella.

4. **Fertilizer products not containing a pesticide**, such as sphagnum moss used as plant growth media to retard damping-off.

5. **Plant inoculant products** consisting of microorganisms applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system. See *40 CFR 152.6(g)(2)*.

6. **Soil amendment (e.g., vermiculite, sand, lime) products** containing a substance or substances added to the soil for the purpose of improving soil characteristics favorable for plant growth. See *40 CFR 152.6(g)(3)*. Soil amendments are intended to increase porosity, retain moisture, adjust pH, and other uses intended to benefit crop production. For example, although normally considered to be a fungicide or miticide, products containing sulfur when applied to soil to solely adjust the pH have historically not been subject to registration. Sulfur may also have non-pesticidal uses as a foliar plant nutrient at low concentrations.

7. **Plant nutrient products** consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants. See *40 CFR 152.6(g)(1)*.

E. Antimicrobial Products Used Solely in Processed Foods or Feeds, in Beverages, or in Pharmaceuticals

The Antimicrobial Regulation Technical Correction of 1998 (ARTCA) amended the Food Quality Protection Act (FQPA) to clarify the jurisdictions of EPA and FDA regarding food use antimicrobial pesticides. Following is a brief summary of ARTCA's jurisdictional clarifications. For further details, see FDA's July 1999 "Antimicrobial Food Additives Guidance Document" at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm077256.htm*.

The following activities constitute food processing and any food subjected to these activities becomes a "processed food" within the meaning of 40 CFR 152.5 (definition of a pest): canning, freezing, cooking, pasteurization, or homogenization, irradiation, milling, grinding, chopping, skinning, cutting or peeling. Processing also includes carcasses post-slaughter which includes skinning, eviscerating and quartering. These post-slaughter activities result in "processed food" within the meaning of 40 CFR 152.5. In addition, seafood that is harvested is processed food. Activities done post-harvest to seafood include handling, storing, preparing, heating, eviscerating, shucking or holding. Substances used in these processes against microbes in or on the processed food are not pesticides under FIFRA and are regulated solely by the FDA under the FFDCA.

The following post-harvest activities do not constitute food processing within the meaning of 40 CFR 152.5: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems and husks. These processes do not meet the definition of "processed food" and are not subject to the exclusions of 40 CFR 152.5. Therefore, pesticides used during the processes are FIFRA pesticides and are regulated by EPA under FIFRA.

F. Products with No Pesticidal Claims

Products that are not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate, or regulate the growth of plants are not considered to be pesticides. Some of these products may appear to be pesticides, but are not considered as such unless pesticidal claims are made on their labeling or in connection with their sale and distribution. *40 CFR 152.10* lists products which fall under this category.

1. **Deodorizers, bleaches, and cleaning agents.** OPP has treated products bearing claims for sanitizing or disinfecting properties as pesticides requiring registration. For example, a bleach which consists of 5.25% sodium hypochlorite would likely require registration if the label states that bacteria will be killed at certain doses. An identical bleach would not likely need to be registered if the labeling only claims to whiten, bleach or clean laundry, and does not contain an explicit or implicit antimicrobial claim.

   EPA has also posted guidance on its web page entitled, "Determining If a Cleaning Product is a Pesticide under FIFRA" (http://www.epa.gov/pesticides/factsheets/pest-). This document provides details on what kinds of cleaning-related claims may be considered pesticidal versus non-pesticidal.

2. **Attractants.** Products that are intended only to attract pests for survey or detection purpose, that are labeled accordingly, and which contain no toxicants.

3. **Physical barrier.** Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants. Examples might include: pruning for trees; latex or asphalt tree wound dressings that make claims of preventing the entrance of insects or fungi into fresh cut surfaces of plants; cocoa bark or pine bark mulches that claim suppression of weed growth; black plastic or tar-paper used to suppress weeds or prevent the entrance of insects.

III. What makes a product a pesticide?

The term "pesticide" is defined at *FIFRA 2(u)*. One of the most important words in the FIFRA definition of "pesticide" is "intended." One of the analytical steps to determining whether a product is a pesticide is to consider whether the product is "intended" to be used as a pesticide. Products are generally considered to be pesticides if they are *intended* for preventing, destroying, repelling, or mitigating any pest or *intended* for use as a plant regulator, defoliant, or desiccant. OPP determines **intent** by examining claims on the label, advertising, composition/use, and/or mode of action of the product as distributed or sold. Section *40 CFR 152.15* sets forth the criteria

to help establish intent. If the regulatory criteria are met the label reviewer can conclude that the product is a pesticide and must be registered. The regulatory criteria are described below:

A. Claims

If a person who distributes or sells the product claims, states or implies by labeling or otherwise (such as, advertising, collateral literature, or verbal statements), that the product can or should be used as a pesticide or that the product contains an active ingredient and that it can be used to manufacture a pesticide, then the product is a pesticide. *40 CFR 152.15(a).*

B. Composition

If a product is composed of one or more active ingredients that have no other significant, commercially valuable use other than for a pesticidal purpose or for use in manufacturing a pesticide then the product historically has been considered to be a pesticide. *40 CFR 152.15(b).* For example, a company markets a granular product that has labeling identifying the presence of 2,4-D, directions to apply it to lawns at a certain dosage rate, and warns the user about over-application, but does not claim that broad-leaved weeds will be killed, is the product a pesticide? Most likely, the product is a pesticide because 2,4-D is a well-known herbicide and has no other significant commercially valuable use.

C. Knowledge that the Substances Will Be Used as a Pesticide

Even if pesticidal claims are not made for the product, if the person who distributes or sells the substance has actual or constructive knowledge that the substances will be used, or is intended to be used, for a pesticidal purpose, the product is a pesticide product required to be registered. *40 CFR 152.15(c).*

D. Plant Growth Regulators

A plant growth regulator, through physiological action, is intended to accelerate or retard growth, or alter plant behavior or the produce of the plant. Examples of claims that can be considered to be plant growth regulator claims include: increased blossom set, stimulation of root or plant growth, prevention of sucker growth, delayed onset of sprouting of harvested root crops, abscission stimulation of fruit crops, stimulates plant growth and fruiting, promotes fruit and seed development, increases stem and stalk strength, and increases fruit size. Whether a product is considered to be a plant growth regulator depends on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. The composition of the product may aid in making the determination.

1. **Plant hormones and other compounds,** such as auxins, cytokinins, and gibberellins have no other uses except as plant growth regulators. Therefore, the presence of any of these types of compounds generally causes a product to be considered a plant growth regulator.

2. **A vitamin-hormone horticulture product** is not a plant growth regulator if the product is not intended for use on food crops and is labeled accordingly, and meets the other

criteria 40 CFR 152.6(f). Vitamin-hormone horticulture products containing auxins, cytokinins, and gibberellins are exempt from registration if these criteria are met.

IV. Pesticides exempted from the requirements of FIFRA

The Agency has exempted certain pesticides from regulation under FIFRA under the authority of *FIFRA 25(b)* because the pesticides have been determined to be (1) adequately regulated by another Federal agency or (2) of a character which is unnecessary to be subject to FIFRA. Just because a pesticide is exempted under FIFRA, however, does not mean that the Federal Food, Drug and Cosmetic Act (FFDCA) or state laws may not apply. For example, even if a pesticide product meets the conditions for exemption from regulation under FIFRA, it might still be subject to FFDCA requirements to have a tolerance or tolerance exemption if there is a pesticide chemical residue on food. The following are examples of products exempted from FIFRA under 25(b):

A. Pesticides Regulated By Another Federal Agency

1. **Certain Biological Control Agents.** Biological control agents are generally exempt from FIFRA regulation. *40 CFR 152.20(a)*. However, the Agency has determined (*40 CFR 152.20(a)(3)*) that the following biological control agents are *not exempt* and are subject to FIFRA.

   (a) Eucaryotic microorganisms, including protozoa, algae, and fungi;

   (b) Procaryotic microorganisms, including bacteria; and

   (c) Viruses.

B. Pesticide Not of a Character Requiring FIFRA Regulation

1. **Treated Articles or Substances.** The Agency has determined that an article or substance containing a pesticide to protect the article or substance itself does not require registration and is exempt from all provisions of FIFRA, provided the pesticide is registered for such use and bears appropriate directions for such use. Claims for the preserved article or substance are limited to the protection of the article or substance itself. See *40 CFR 152.25(a)* and *PR Notice 2000-1*. Examples include:

   (a) Paints that have been treated with antimicrobial pesticides and bear claims that the dried paint film will be resistant to mold or mildew. Paints with expressed or implied claims made for protection of the surface beneath the paint film or for preventing or destroying mold or mildew on the surface of the paint or beneath the paint are not within the treated articles exemption and, therefore, will require registration under FIFRA. Paints that are to be used in canneries, breweries, hospitals, or other areas where a crucial consideration is prevention of bacteria or

mold that would pose a health risk are generally not subject to the treated articles exemption and, therefore, are regulated under FIFRA.

(b) Shower curtains treated with a fungicide to retard mildew growth; lumber treated with a wood preservative; bathroom caulks impregnated with a mildewcide; and fabrics and leather treated with preservative compounds (all of which uses are intended to protect the treated articles themselves) are other examples of products that have been historically exempted from the requirements of FIFRA.

(c) Shirts and other articles of clothing treated with an insecticide to repel mosquitoes and other insect pests are examples of products treated with insecticides that require registration of the article of clothing. Because the treatment would be for the benefit of the wearer rather than to protect the clothing, the treated article exemption would not apply and the article of clothing would be subject to registration.

2. **Pheromones and Pheromone Traps**

Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient are not subject to FIFRA regulation. Refer to *40 CFR 152.25(b)(1), (b)(2), and (b)(3)* to determine whether a substance is a pheromone for purposes of this exemption. Refer to *40 CFR 152.25(b)(4)* to determine whether the pheromone trap falls within the exemption. Pheromones are chemicals used in intra-species communication. A chemical used in inter-species communication (i.e., using fox urine to repel rabbits) is an "allomone" and would be subject to FIFRA.

3. **Preservatives for Biological Specimens**

(a) Embalming Fluids. Mortuary supplies intended to prevent or mitigate mold and bacteria on or in human cadavers are exempt. *40 CFR 152.25 (c)(3)*. The rationale for this exemption is that the use is limited to embalmers and morticians who are specially trained to handle such products and do not require the protection afforded by registration. The general public would not be exposed to such products.

(b) Animal and animal organ preservatives Products used to preserve animal or animal organ specimens in mortuaries, laboratories, hospitals, museums, and institutions of learning are exempt. *40 CFR 152.25(c)(2)*.

(c) Preservatives for Laboratory Analysis. Products used to preserve the integrity of milk, urine, blood, or other bodily fluids for laboratory analysis are exempt. *40 CFR 152.25(3)*.

3. **Foods.** Products consisting of foods and containing no active ingredients, which are used to attract pests, are exempt. *40 CFR 152.25(d)*.

4. **Natural Cedar.** Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:
   (a) The product consists totally of cedarwood or natural cedar;
   (b) The product is not treated, combined or impregnated with any additional substance(s); and
   (c) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as "arthropods", "insects," "bugs," or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks. The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture. *40 CFR 152.25(e)*.

5. **Minimum Risk Pesticides.** 40 CFR Section 152.25(f) (previously 40 CFR 152.25(g)) exempts certain "minimum risk pesticides" from the requirements of FIFRA if they satisfy all the conditions described in that provision (i.e., 152.25(f)(1)-(3)). Some of the conditions of exemption specifically relate to a product's labeling (see *152.25(f)(3)*). For further information, *PRN 2000-6:* "Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues". See also EPA's webpage for Minimum Risk Pesticides http://www.epa.gov/pesticides/biopesticides/regtools/25b_list.htm and the list of permissible inerts http://www.epa.gov/pesticides/biopesticides/regtools/25b/25b-inerts.htm

V. Is the product a device and, therefore, not a pesticide?

FIFRA defines a device as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom" *FIFRA 2(h)*. FIFRA does not require the registration of pesticidal devices. Devices, however, are subject to a number of FIFRA's provisions including, labeling requirements and establishment number identifying the location where the device was produced. See *40 CFR 152.500* and Chapter 13 of EPA's Pesticide Registration Manual (*http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices*) for more information on devices and additional FIFRA requirements.

Equipment that generates a pesticide (e.g., a CO_2 or ozone generator) may or may not be considered a device. The reviewer should consult with the PM if there is any question about the product's status.

Revised March 2018

Label Review Manual

Chapter 3: General Labeling Requirements

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Table of Contents

What's changed in this version?

- Updated cover page.
- Added *Table of Contents.*
- Added *What's changed in this version?* section.
- Reformatted text and style to improve readability.
- Updated hyperlinks.
- Reorganized sections and subsections.
- Added note on using supplemental distributor labeling terminology.
- Updated web-distributed labeling section to include container label language example.
- Updated label submission requirements section to include e-Submission methods.
- Added note on submitting five replicates for paper copy submissions.
- Updated final printed labeling section to reflect current practices.
- Updated MOA symbol reference from PR Notice 2001-5 to PR Notice 2017-1.
- Updated first aid statement location per EPA's guidance document *EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68*.

I. Introduction

This chapter describes the various types of pesticide labels and also addresses general labeling requirements concerning text format, label contents and placement, mandatory versus advisory statements, and final printed labeling. The last section of this chapter explains how to submit labels for EPA review.

II. Types of labels and labeling

This section defines "label" and "labeling" and discusses the various types of pesticide labels and labeling. Final printed labeling is discussed separately towards the end of this chapter.

A. Definitions

FIFRA 2(p) defines pesticide "label" and "labeling" as:

LABEL	The written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.
LABELING	All labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time, or to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

B. Master label

A master label contains all of the approved uses for a given pesticide product and all associated labeling. Master labels must be submitted for EPA approval. Approved master labels are stamped "ACCEPTED" and placed in the official record. Labeling for a given product must not contain any text beyond that which is approved in the master label (except for supplemental labeling as explained below).

C. Final printed labeling

A final printed labeling is the label or labeling of a pesticide product when it is distributed or sold. Pursuant to 40 CFR 156.10(a)(6), with certain limited exceptions, "final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency."

D. Sub-label or split-label

A "sub-label" (or "split-label") contains a subset of the approved uses under a given master label, but is a complete, standalone label, containing all of the required labeling elements. A registrant may distribute or sell a product under a sub-label provided that in limiting the uses identified on the label, no changes would be necessary to the precautionary statements, use classification, or packaging of the product. 40 CFR 152.130(b). Since sub-labels only contain text which already appears on the master label, they are not stamped "ACCEPTED" separately. Final printed labeling must be submitted according to 40 CFR 156.10(a)(6). A distributor product with a sub-label containing an alternate brand name must meet the requirements of 40 CFR 152.132 and 40 CFR 156.10(b)(2)(ii).

Registrants submitting a sub-label should clearly:

- Indicate when the sub-label does not contain the entire use profile of the product.
- Annotate specific label changes on the sub-label.
- If proposed changes to a sub-label require changes to the master label, the registrant must submit a new master label incorporating and annotating any additions or changes.
- Indicate at the top of the label whether it is a "Sub-Label" or "Split-Label," for example:

SUB-LABEL - Revises Master Label dated XX-XX-XX

A new master label containing all currently-approved uses is required when a sub-label is submitted with additions not on the approved master label. Only the master label will be stamped "ACCEPTED." The previously-approved labeling may be distributed or sold for a period of 18 months after approval of the revision. 40 CFR 152.130(c).

E. Supplemental labeling

Supplemental labeling contains modifications to the pesticide label since the last-approved master label (e.g. new use, change application timing). Supplemental labels must be submitted for EPA approval, and approved labels are stamped "ACCEPTED" and placed in the official record. Supplemental labels are partial labels distributed with the product by the registrant or distributors in addition to the complete product label. Since these are partial labels, they must bear a statement referring the user to the product label for complete directions, precautions, and a statement that both the product label and supplemental labeling must be in the possession of the user when using the product. Compliance with both the product label and supplemental labeling is required to safely and effectively use the product.

Supplemental labeling must include the following:

- Product name
- EPA Registration Number
- Restricted use classification statement (if applicable)
- "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
- "This labeling must be in possession of the user at the time of application."
- "Read the label affixed to the container for [*product name*] before applying."
- "Use of [*product name*] according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for [*product name*]."

Typically, supplemental labeling will be incorporated into the master label at the next printing of the product label (final printed label) or within 18 months, whichever comes first. However, there are circumstances when this might not be done; for example, if the directions for use on the supplemental labeling are subject to continual, frequent change (e.g., California aerial application county restrictions can change every six months.). Supplemental labeling must be approved prior to distribution.

Supplemental labeling also includes state registration of special local need (SLN) under FIFRA 24(c). Refer to 40 CFR 162.153(e)(3) for state registration label requirements.

F. Distributor label

A distributor label is used when a product is registered to one company, but is distributed or sold (known as "supplemental distribution") by another company (known as the "distributor" or "sub-registrant"). 40 CFR 152.132. Distributor labels are not submitted for approval, but a Notice of Supplemental Distribution must be submitted to EPA before supplemental distribution of the product. The registrant is responsible for the contents of both the distributor product and the distributor label.

A distributor label must be the same as that of the registered product label *except for:*

- Product name
- Distributor name and address
- EPA Establishment Number
- EPA Registration Number (a third set of numbers is added at the end denoting the distributor's company number, e.g. EPA Reg. No. 1234-56-7890.)
- Product claims (specific claims may be deleted so long as no other changes are necessary, but new claims cannot be added)
- Warranty statements (if allowed by contract between the registrant and the distributor and such change is not false or misleading)

- The term "supplemental distributor labeling" is sometimes used, but is not proper EPA terminology and is often confused with the term "supplemental labeling." The correct term is "distributor label." A supplemental label is used to add new uses or directions for a product, while a distributor label cannot include any uses or directions that differ from the registered product's labeling.

G. Collateral labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written, printed or graphic matter referenced on the label or accompanying the product are known as "collateral labeling." Such labeling is subject to applicable requirements of FIFRA and the Agency's regulations. In addition, collateral labeling may not bear claims or representations that substantially differ from those accepted in connection with registration of the product. FIFRA 12(a)(1)(B). Collateral labeling must be submitted along with the application for registration and must be accepted by EPA before it can be referenced on the label and/or distributed along with the product. However, official publications of certain federal and state agencies and institutions referenced on or accompanying a label or labeling are exempted by FIFRA 2(p)(2)(B) from the definition of label and labeling, and therefore do not require review.

H. Safety data sheets

The Occupational Safety and Health Administration (OSHA) has direct authority over Safety Data Sheets (SDS), formerly called Material Safety Data Sheets (MSDS). When an SDS is distributed with a pesticide it becomes a part of the pesticide labeling because it is accompanying the product. FIFRA 2(p)(2)(A). Therefore, if an SDS includes warnings, precautions or any other information that conflict with the FIFRA-approved label, it could be misleading to users of the pesticide and therefore cause the pesticide to be considered misbranded and unlawful for sale or distribution. For example, in 2012 OSHA adopted a revised Hazard Communication Rule for SDSs which utilizes the criteria for signal words adopted by multiple countries under the Globally Harmonized System (GHS) for hazard communication language and symbols. EPA has not adopted the GHS criteria, and thus an OSHA SDS may have a signal word that differs from the one EPA requires for a pesticide product label. PR Notice 2012-1 explains how a company can explain and justify such a difference if it occurs in order to prevent users from being misled by the inconsistencies.

I. Web-distributed labeling

A web-distributed labeling is a legally-valid, enforceable labeling for a pesticide product that is accessible online, and can be tailored to provide users with instructions specific to the use site and the state in which the product will be used. PR Notice 2014-1 provides guidance on web-distributed labeling, with instructions on how to submit websites and web-distributed labels for review.

To add web-distributed labeling, the container label should include a statement at the beginning of the Directions for Use section, immediately after any required text, that:

- directs users to the website with the web-distributed labeling;
- indicates that the web-distributed labeling is legally valid; and
- informs users that they may choose which label to follow (container vs. website) in cases where the labels conflict. In areas of conflict, the user must use only one set of labeling instructions.

EXAMPLE OF CONTAINER LABEL DIRECTIONS FOR WEB-DISTRIBUTED LABELING

You may obtain additional labeling from [*website address*]. If using the additional labeling to apply the product, you must possess a copy of this additional labeling at the time of application. It is a violation of federal law to use this product in a manner inconsistent with its attached label or any additional labeling, including any web-distributed labeling. In instances where the additional web-distributed labeling conflicts with the container label, the user may choose a single, valid version of the labeling to follow. However, for areas of overlap or conflict, the user must use only one set of labeling instructions, either the attached container label or the web-distributed labeling. Do not mix and match labeling directions.

The release for shipment date is in DDMMYYYY format and can be found on the neck of the container. The unique identifier format is AAAAA-11111 and it can be found on the neck of the container below the release for shipment date.

J. Websites

If a label references a company's website, either by listing a web address or URL, including a Quick Response Code (QR Code), or using similar identifiers that direct to a website, then the website becomes "labeling" under FIFRA and is subject to EPA review. PR Notice 2014-1. If the website contains false or misleading information, then the product may be considered misbranded and unlawful to sell or distribute under FIFRA 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA considers misbranding. Also, regardless of whether a website is referenced on a product's label, claims made on the website may not substantially differ from approved claims related to that product. Claims that do substantially differ from what was approved may result in a pesticide product that is unlawful to sell or distribute under FIFRA 12(a)(1)(B).

K. Non-FIFRA labeling

Some labels submitted to the Agency have information addressing non-FIFRA issues (e.g., Department of Transportation (DOT) shipping rules; New York City fire code symbols; Hazardous Materials Identification System (HMIS), National Paints and

Coatings Association (NPCA), and National Fire Protection Association (NFPA) hazard codes and rating systems; Food and Drug Administration or Department of Agriculture numbers; and bar codes). A registrant may choose to place such text on the label but the text may not replace, obscure, conflict with, or supersede the FIFRA-required text.

III. Label format

A. Prominence and legibility

All words, statements, graphic representations, designs or other information that are legally required to appear on labeling must be clearly legible, conspicuous, and easily understood to the reader. All required label text must be set in 6-point or larger type, appear on a clear contrasting background, and not be obscured or crowded. 40 CFR 156.10(a)(2).

B. Label placement on container

The label must appear on or be securely attached to the immediate container of the pesticide product. "Securely attached" means that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package as customarily distributed or sold. 40 CFR 156.10(a)(4)(i). Requirements for label placement on tank cars and other bulk containers during transport and storage are described in 40 CFR 156.10(a)(4)(ii).

C. Front panel minimum type size requirements

All required front panel warning statements (signal word, child hazard warning, and in certain cases the first aid statement) must be grouped together, and appear with sufficient prominence relative to other front panel text and graphics. 40 CFR 156.60.

The tables below show the minimum type size requirements and type size examples based on various front panel sizes.

FRONT PANEL MINIMUM TYPE SIZE REQUIREMENTS[1]		
Front Panel Label Size (in^2)	**Minimum Signal Word Type Size**	**Minimum KOOROC Type Size**
≤5	6 point	6 point
>5 – 10	10 point	6 point
>10 – 15	12 point	8 point
>15 – 30	14 point	10 point
>30	18 point	12 point

[1] No type size on any label can be less than 6 point.

Example for front panel size ≤5 in^2				
6 point	POISON	DANGER	WARNING	CAUTION
6 point	KEEP OUT OF REACH OF CHILDREN			
6 point	Keep Out of Reach of Children			
Example for front panel size >5-10 in^2				
10 point	POISON	DANGER	WARNING	CAUTION
6 point	KEEP OUT OF REACH OF CHILDREN			
6 point	Keep Out of Reach of Children			
Example for front panel size >10-15 in^2				
12 point	POISON	DANGER	WARNING	CAUTION
8 point	KEEP OUT OF REACH OF CHILDREN			
8 point	Keep Out of Reach of Children			
Example for front panel size >15-30 in^2				
14 point	POISON	DANGER	WARNING	CAUTION
10 point	KEEP OUT OF REACH OF CHILDREN			
10 point	Keep Out of Reach of Children			
Example for front panel size >30 in^2				
18 point	POISON	DANGER	WARNING	CAUTION
12 point	KEEP OUT OF REACH OF CHILDREN			
12 point	Keep Out of Reach of Children			

IV. Label contents and placement

Listed below are the various sections of the label in the *approximate* order they should appear on a label. Each section corresponds to the chapter in this manual which discusses that particular part of the label in more detail. Different formats are used for certain classes of products (e.g., rodenticide baits). Unless otherwise noted, panel sub-headings in this section represent the panel(s) on which the label information listed under each sub-heading is recommended for inclusion.

A. Front panel label contents

1. Restricted use pesticide statement (Chapter 6)

A product classified as a "restricted use" pesticide (RUP) under FIFRA Section 3(d)(1)(c) must include the required RUP statements at the top of the front panel, under the heading "Restricted Use Pesticide." 40 CFR 156.10(i)(2).

2. Product name, brand or trademark (Chapter 12)

The name, brand or trademark under which the pesticide product is sold must appear on the front panel of the label. 40 CFR 156.10(b)(1).

3. Ingredient statement (Chapter 5)

The name and percentage by weight of each active ingredient and the total percentage by weight of all other/inert ingredients must be on the front panel of the label. It must also be on the outside container or wrapper if the ingredient statement is not clearly visible. If the size or form of the product package makes it impractical to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere. 40 CFR 156.10(g)(2).

4. Keep Out of Reach of Children statement (Chapter 7)

The statement "Keep Out of Reach of Children," also known as KOOROC or the child hazard warning statement, must be placed on the front panel of the label near the signal word. EPA may waive the child hazard statement requirement if a product meets certain criteria. EPA may also approve an alternative child hazard warning if it more appropriately reflects the product's use or exposure to children. 40 CFR 156.66.

5. Signal word (Chapter 7)

The signal word corresponding to the highest/most toxic acute toxicity category to which a pesticide product is assigned must appear on the front panel of the label. Products classified as Toxicity Category I based on acute oral, acute dermal, or acute inhalation hazard; or certain inert ingredients must also include the word "**Poison**" (in red on a contrasting background color) next to the signal word DANGER, with the skull and crossbones symbol in close proximity. 40 CFR 156.64.

6. First aid for toxicity category I (Chapter 7)

Each product must bear a first aid statement if the product has systemic effects in Toxicity Category I, II or III, or skin or eye irritation effects in Toxicity Category I or II. First aid statements for products classified as Toxicity Category I must appear on the front visible panel unless EPA permits reasonable variations in placement of the statement and a reference such as "See side/back panel for first aid statement." appears on the front panel. 40 CFR 156.68 and *EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68*.

7. Net contents/net weight (Chapter 17)

The net contents/net weight statement identifies the weight or volume of a pesticide in the container. There is no required location for this statement, but the preferred location is at the bottom of the front panel below the company name and address.

B. Other label contents

1. EPA registration number (Chapter 14)

The EPA registration number is the single most important piece of information for tracking pesticide products. This identifier must appear on the label of the product, preceded by the phrase "EPA Registration No.," or "EPA Reg. No.," and be set in type size and style similar, and run parallel to, other print on that part of the label on which it appears. 40 CFR 156.10(e).

2. EPA establishment number (Chapter 14)

The EPA establishment number identifies the final physical location where the pesticide product was produced or labeled. This identifier must be preceded by the phrase "EPA Est. No.," and may appear on any suitable location on the label

or immediate container; however, it must appear on the wrapper or outside container of the package if the number cannot be clearly read through the wrapper or container. 40 CFR 156.10(f).

3. Company name and address (Chapter 15)

The name and address of the producer, registrant, or person for whom the product is produced. 40 CFR 156.10(a)(1)(ii).

4. Mode of action classification symbol (Chapter 11)

When applicable, the mode of action (MOA) classification symbol is recommended to be placed in the upper right hand corner of the front panel of end-use product labels, although it may be placed elsewhere on the label. PR Notice 2017-1.

5. Hazard and precautionary statements (Chapter 7)

Hazard and precautionary statements that are not required on the front panel may appear on other panels of the label. These statements must appear together on the label under the heading "Precautionary Statements" and under the appropriate subheadings.

6. Hazards to humans and domestic animals (Chapter 7)

When an acute hazard may exist to humans or domestic animals, the label must include precautionary statements describing the particular hazard, route(s) of exposure and precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph should be placed under a subheading *similar to* "Hazards to Humans and Domestic Animals," and must be preceded by the appropriate signal word. The phrase "domestic animals" may be omitted if domestic animal exposure is not expected. These statements may be placed on any panel of the label. 40 CFR 156.70.

7. First aid for toxicity category II, III, or IV (Chapter 7)

First aid statements for products classified as Toxicity Category II, III, or IV may appear on the front, side, back, or inside panel, with a referral statement such as "See side/back/inside panel for additional precautionary statements." on the front visible panel near the signal word. Products classified as Toxicity Category IV are not required to include a first aid statement, but it is highly recommended. PR Notice 2001-1 and *EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68*.

8. Environmental hazards (Chapter 8)

Where environmental hazards exist, including hazards to non-target organisms, statements that identify the nature of the hazard and the precautions necessary to avoid potential accident, injury, or damage must appear on the label, under the heading "Environmental Hazards." These statements may appear on any panel of the label. 40 CFR 156.80.

9. Physical or chemical hazards (Chapter 9)

When applicable, flammability and/or explosivity statements and the various precautions to be taken must be identified on the label. Warning statements pertaining to other physical or chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis. These statements should be placed under the subheading "Physical or Chemical Hazards" on any panel of the label. 40 CFR 156.78.

- The regulations only require a heading *similar to* "Physical or Chemical Hazards." The heading "Physical and Chemical Hazards" is also acceptable.

10. Worker protection labeling (Chapter 10)

Worker protection statements are required for pesticide products in use settings covered under the Worker Protection Standard (WPS) and in non-WPS settings. 40 CFR 156 Subpart K.

11. Directions for use (Chapter 11)

This section of the label provides instructions for how to safely and effectively use the pesticide product, including where and when to use it, which pest(s) to use it on, how much to apply, and which types of application equipment are appropriate. This section also includes certain WPS statements and any other information that is necessary to protect human health and the environment. These instructions must be placed under the heading "Directions for Use" and may appear on any panel of the label. 40 CFR 156.10(i).

12. Warranty statement (Chapter 12)

This is a disclaimer included *voluntarily* on most pesticide products by the registrant. When it is included, it must conform to specific requirements.

13. Storage and disposal (Chapter 13)

Instructions for storing the pesticide product and disposing of unused pesticide and its container must be placed under the heading "Storage and Disposal." 40 CFR 156.10(i)(2)(ix).

C. Container label booklet

A booklet or other "pull-off" type labeling may be used when it is not feasible to fit the entire label text directly on the product container. The table below lists the label contents that must be on the label which is on or "securely-attached" to the container, subject to the exceptions in 40 CFR 156.10, and the minimum contents that should be on the booklet or other "pull-off" labeling. The securely-attached container label should also include a referral statement to the booklet for Directions for Use and other information, as applicable.

Label Content	Securely-attached container label	Detachable label booklet
Name and address of the producer, registrant, or person for whom produced	✓	✓
Restricted Use statement (if applicable)	✓	✓
Product name, brand, or trademark	✓	✓
Signal word, including skull and crossbones symbol (if applicable)	✓	✓
"Keep Out of Reach of Children"	✓	✓
Precautionary Statements, including First Aid and Hazards to Humans and Domestic Animals statement	✓	✓
EPA Registration Number	✓	✓
EPA Establishment Number	✓	✓
Ingredient statement	✓	
Net Weight/ Net Contents	✓	
Storage and Disposal	✓	
Referral statement to booklet for Directions for Use (if applicable)	✓	
Directions for Use		✓

V. Mandatory and advisory statements

Label and labeling statements need to be clearly mandatory or advisory in order to avoid confusion that may cause misuse and/or adverse effects to human health and the environment and to avoid making key requirements unenforceable. PR Notice 2000-5.

A. Mandatory statements

Mandatory statements relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects on the environment, which is defined in FIFRA. Mandatory statements include directions for use and restrictions that direct the user to take or avoid specific actions. The directions and restrictions specify where, when and how a pesticide is to be applied. Mandatory statements are generally written in imperative or directive sentences. Either EPA or the registrant may develop mandatory labeling statements. When writing mandatory statements, both EPA and the registrant need to ensure that such statements are necessary to ensure proper use of a pesticide and to prevent unreasonable adverse effects on the environment. The following are examples of mandatory statements:

"Wear chemical-resistant gloves."

"Do not apply within 66 feet of wells."

"Do not apply directly to water."

"Keep away from heat, sparks and open flame."

"Do not enter into treated areas for 12 hours."

"Apply immediately after mixing."

"Do not apply when wind speed exceeds 15 mph."

B. Advisory statements

Advisory statements provide information to the product user on such topics as product characteristics and how to maximize safety and efficacy while using the product. Such statements are acceptable as long as they do not conflict with mandatory statements, are not false or misleading, and do not otherwise violate statutory or regulatory requirements.

Advisory statements are best written in descriptive or nondirective terms. Phrasing advisory statements in straightforward, factual terms minimizes the possibility that they will conflict with mandatory statements. The use of certain words such as "should",

"may" or "recommend" in advisory statements may erroneously mislead the user to believe that he/she must comply with such statements; or conversely, that a non-recommended use is still permitted, leading to a possible misuse. Advisory statements should explain the purpose or benefit of doing something, instead of just asserting that it should be done. The following are examples of problematic statements and preferred alternatives:

Precautionary Statements

Problematic	"Latex gloves are recommended."
Preferred	"Latex gloves provide the best protection."

Physical and Chemical Hazards

Problematic	"It is preferable to open containers of aluminum phosphide products in open air as under certain conditions they may flash upon opening. Containers may also be opened near a fan or other appropriate ventilation which will rapidly exhaust contaminated air."
Preferred	"Opening aluminum phosphide containers outdoors or indoors near an exhaust fan or other ventilation helps to ensure that the gas will be rapidly dispersed if the product flashes."

Directions for Use

Problematic	"Tank mixtures should be applied immediately after preparation. If for any reason this is not possible, ensure that sufficient agitation has been provided to remix all products and check for complete resuspension prior to application."
Preferred	"Applying the product immediately after preparation will help to ensure that it is in suspension. If application is delayed, agitation to remix the products and checking for resuspension will ensure proper blending."
Problematic	"Factors such as depth to the drain system, soil type, and degree of compaction should be taken into account in determining the depth of treatment."
Preferred	"The depth of treatment depends on the depth of the drain system, soil type, and degree of soil compaction."

Problematic	"It may be necessary to treat along one side of interior partition walls if there are cracks in the slab, plumbing entry points, existing termite infestations, or other conditions which would make treatment appropriate."
Preferred	"Treatment along one side of interior partition walls where there are cracks in the slab, plumbing entry points, existing termite infestations, or evidence of other means of access prevents further infestation."
Problematic	"The spray mixture should be directed to the soil around the base of the cotton plants. Care should be taken to prevent the spray from striking the cotton leaves as injury will occur. The use of leaf lifters or shields on application equipment is recommended to avoid spraying the cotton foliage."
Preferred	"Directing the spray mixture around the base of the cotton plants and using leaf lifters and shields on application equipment will help minimize foliage contact and plant injury."

VI. Label submission requirements

Draft labels submitted for EPA review must follow the application procedures in 40 CFR 152.50. In addition, registrants are encouraged to follow the other steps outlined below to facilitate review. Registrants are also highly encouraged to submit applications and labels electronically, which increases review efficiency and improves the quality of labels provided to the public via the Pesticide Product Label System.

A. Paper submissions

Paper submissions for new registrations or amendments must include five copies of all draft labeling (typescript or mock-up). 40 CFR 152.50. For amendments, the Agency requests one marked copy of the draft label, indicating proposed changes. The other four copies should be "clean" and not annotated in any way, containing the proposed label changes.

All copies must be legible and should be of suitable quality for making legible photocopies. Draft labels should be submitted on standard, letter-sized 8 ½" X 11" paper, set in at least 12-point font size.

- Under current practices, submitting five copies of draft labeling may be unnecessary. Registrants should consult with the product manager or registration ombudsman before submitting a paper application with labels.

B. Electronic submissions

Registrants can submit draft labeling electronically using various methods depending on the type of application package.

- **Electronic label with paper application:** An electronic label ("e-label") as a text-searchable .pdf file may be submitted on a CD-ROM or DVD along with a paper application. In this case, only one paper copy of the label needs to be submitted with the paper application. A Certification with Respect to Label Integrity form must be completed and submitted with the e-label.

- **Electronic label with electronic application:** An e-Submission package can be generated and submitted using the Pesticide Submission Portal (PSP) through EPA's Central Data Exchange (CDX) Network, the e-Dossier Builder, or by using an XML file creation application. The e-label must be a text searchable .pdf file. No paper copies for any documents, including labeling, are needed with an e-Submission.

Revised December 2011

Label Review Manual

Chapter 4: Types of Label Reviews

http://commons.wikimedia.org, photo by "Daderot"

I. Introduction

Label reviews are conducted for many types of submissions. How a reviewer proceeds with a label review depends on the type of action proposed by the registrant and whether the submission is a new submission (first time submitted to the Agency) or a follow-up to a previous submission.

When a registrant submits information pertaining to several products that are similar in composition or a series of dilutions (products that have the same active ingredient (a.i.) and other ingredients so when diluted they may be considered identical), every effort should be made to route and review these submissions together to ensure consistency of labeling decisions.

Labeling use patterns (sites and pests) are captured for the purpose of registration, re-registration and registration review and are internally available in the Office of Pesticides Program Information Network (OPPIN) database. This will soon become PRISM, the "Pesticide Registration Improvement System". It is very important that the Agency be able to easily and accurately identify the registered uses for pesticide products. OPPIN/PRISM captures registration numbers, active ingredients, use sites, etc. from approved Section 3 and Section 24(c) labels. OPPIN/PRISM provides the basis for determining what products are currently registered and their use patterns. The registrant must submit and maintain a "Master Label" bearing all registered uses for each registered product (whether or not they use sub-labels or split- labels as described in Chapter 3 IV.B). The regulations allow the reviewer to request the complete text of the proposed amended label at any time. *40 CFR 152.50(e).*

Electronic Label Review

OPP has begun to use electronic label review to assist in the review and approval of pesticide labels.

Q: What is E-Label Review?

A: Use of a text searchable .pdf label during EPA review of any label submission. The label reviewer will use a computer to:

a) *compare* the proposed e-label to the last version to quickly identify changes,

b) *comment* directly on label to indicate any revisions required on the label.

Q: How are e-labels submitted?

A: Registrants should submit a text searchable .pdf of the label on a CD-ROM along with the usual paper application. The paperwork should also include a signed affidavit (see website for form) that states that the paper label matches the e-label. Alternately, the entire application can be submitted in electronic XML format on a CD-ROM. E-labels can be submitted for an initial product application, a label amendment, or a label notification. Resubmission of corrected labels per EPA comments can be sent via email directly to the label reviewer.

Q: What are the technical requirements for e-labels?

A: See website: *http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications*

Critical requirements for e-labels:

a) must be a text searchable .pdf (not image)

b) use of filename syntax*: reg#.yyyymmdd.anything else.pdf.*

c) embed the fonts used in label in the .pdf

Q: What are the benefits to using E-Label Review?

A: The use of electronic labels will help to increase EPA review efficiency and improve the quality of labeling. The comparison function can quickly identify changes (intentional and unintentional) in the proposed version of a label and can be used to ensure conformance to any standardized text requirements. The commenting function allows the reviewer to pinpoint where changes are needed to the la
bel and provide text which the registrant can copy/paste into a
revised label. Using email, rather than paper mail, to exchange comments and revised labels makes the process more efficient and saves paper. Ultimately, e-label review allows the label reviewer and registrant to work interactively to achieve a label stamped "accepted" without any qualifying comments.

II. Labeling and labeling changes that do not require submission or review

A. Distributor Labeling

After a registrant has obtained registration for its pesticide product, a second person or company may then distribute or sell the basic registrant's product under the second person or company's name and address. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product". Supplemental distribution requires an agreement between the basic registrant and the second company (usually referred to as the "distributor"). The registrant confirms the agreement, both the registrant and the distributor company sign the Notice of Supplemental Distribution of a Registered Pesticide Product form (EPA Form 8570-5) for each distributor product, and the registrant submits the original signed form to the Agency. The distributor does not submit the form. (See *40 CFR 152.132* for other requirements). The distributor is considered an agent of the registrant for all purposes under FIFRA and both the distributor and the registrant can be held liable for violations pertaining to the distributor product. *40 CFR 152.132*. The basic registrant is requested to notify EPA in writing if it terminates its agreement with a distributor (See the *Pesticide Registration Manual* (Blue Book)). Distributor labels should *not* be submitted to EPA for review even though distributor products are subject to FIFRA and its implementing regulations. If submitted they will *not* be stamped "Accepted", or even retained in Agency files (See *Chapter 14* for more information on distributor labeling).

B. Minimum Risk Pesticide Exemptions

FIFRA section 25(b) authorizes the Agency to exempt from FIFRA regulation any pesticide which the Agency determines either (1) to be adequately regulated by another Federal agency or (2) to be a character which is unnecessary to be subject to FIFRA. In either case, the pesticide labels do not need to be submitted to the Agency. The Agency has exempted certain minimum risk pesticides by regulations, which are listed at *40 CFR 152.25(f)(1)*. *40 CFR 152.25(f)(3)* and *PR Notice 2000-6* describe additional conditions required to be met in order for the product to be exempt. No false or misleading labeling statements, including those listed in *40 CFR 156.10(a)(5)(i) through (viii)* may appear on an exempt pesticide product. *40 CFR 152.25(f)(3)(iii)*. Only minimum risk inerts from the current updated list may be used to formulate exempt pesticides. *40 CFR 152.25(f)(2)*. The list can be found at http://www2.epa.gov/minimum-risk-pesticides/inert-ingredients-approved-use-minimum-risk-pesticide-products.

C. Non-Notification

There are changes to labels that can be made without notification to the Agency. See *40 CFR 152.46(b)*. PR Notice 98-10 identifies those label topics that can be amended through "non-notification", Please note that other PR Notices may permit certain label modifications by notification for specific Agency initiated label changes. Also be aware that the Antimicrobials Division's notification process is different in some respects from other Divisions. See *PR Notice 98-10* for details relating to notification pursuant to *FIFRA § 3(c)(9)*.

D. Devices

A device is defined by Section 2(h) of FIFRA as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

A device is not required to be registered under *FIFRA sec. 3*. The Agency has issued a policy statement concerning its authority and activities with respect to devices, which was published in the Federal Register of November 19, 1976 (*41 FR 51065*).

A device *is* subject, however, to the requirements set forth in:

(1) *FIFRA sec. 2(q)(1)* and Part 156 of this chapter, with respect to labeling;

(2) *FIFRA sec. 7* and Part 167 of this chapter, with respect to establishment registration and reporting;

(3) *FIFRA sec. 8* and Part 169 of this chapter, with respect to books and records;

(4) *FIFRA sec. 9*, with respect to inspection of establishments;

(5) *FIFRA sec. 12, 13, and 14*, with respect to violations, enforcement activities, and penalties;

(6) *FIFRA sec. 17*, with respect to import and export of devices;

(7) *FIFRA sec. 25(c)(3)*, with respect to child-resistant packaging; and

(8) *FIFRA sec. 25(c)(4)*, with respect to the Agency's authority to declare devices subject to certain provisions of the Act.

III. Labeling and Labeling Changes that require review

The following types of submissions require label review:

- New Active Ingredients and New Uses
- Technical Grade and Manufacturing Use Products
- New Products Containing Existing Active Ingredients
- Labeling Changes by Notification
- Amendments
- Identical or Substantially Similar Products
- Products for which Efficacy Data Must be Submitted
- Special Local Needs, state FIFRA section 24(c) labels
- Experimental Use Permits
- Re-registration

A. New Active Ingredients and New Uses

This type of submission involves a new active ingredient (a.i.) that is currently not registered by the Agency as a pesticide or a new use. The registrant must propose the labeling for such products. The labeling should, however, follow the general label format discussed in Chapter 3. The proposed label text may be modified as a result of the science review.

B. Technical Grade and Manufacturing Use Products

This type of submission involves a product that is used to manufacture or formulate other pesticides (MP). Normally, a technical grade product is registered concurrently with other manufacturing use products or end use products that can be formulated from it. (See description of these types of products below).

1. A technical grade active ingredient (TGAI) is the pesticide chemical in pure form (with impurities) as it is manufactured by a chemical company prior to being formulated into other pesticide products.

2. An MP contains the technical grade active ingredient and may contain intentionally added inerts. A TGAI product is considered an MP, but not all MPs are technical grade products. (See *40 CFR 158.300*; *40 CFR 161.155 (h) and (k)*). The following statement in item 3 below applies to TGAI and MP products.

3. MP registrants are required to identify in their labeling which uses they are supporting for reformulation into end use products. For example:

   "For formulating only into end-use products for (list the use patterns and sites)".

   PR Notice 94-1 recommends specific language. OPP requires that registrants identify at a minimum, the relevant sites, which are listed in the *Pesticide Use Site Index*. *See* also, Appedix A, part 161 of the CFR (Use Pattern Index for Antimicrobial Pesticides). *40 CFR 156.10(i)(2)(iii).* Some MPs list very specific use patterns including pests and in some cases site limitations to assist their formulators in preparing their application for registration.

The labeling of the MP source product used to produce the applicant's product must either:

- List the uses sought by the applicant *or*
- Allow the applicant to formulate the MP product for the uses sought if the applicant satisfies the applicable EPA data requirements for such uses (see *PR Notice 94-1*).

  If an applicant wishes to use an MP product for a use that requires the applicant to first satisfy EPA data requirements in order to reformulate the MP product, the applicant must comply with EPA data submission/compensation obligations to support that use.

4. The labeling of the technical grade or manufacturing use product should include a listing of the use patterns and sites for the end use products to be formulated from the MP, and will also include a statement such as:

   "For Manufacturing or Formulating Use Only"

   At the registrant's discretion, one of the two statements listed below may be added to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or a user group.

   "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s)".

   or

"This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such uses". See *PRN 94-1*.

C. New Products Containing Existing Active Ingredients

This type of submission involves an application for registration of a product containing an active ingredient (a.i.) that is currently registered for use as a pesticide. Label reviewers should consult label recommendations specified in the latest relevant Agency decision documents. Such documents may include the Reregistration Eligibility Decisions (REDs), Interim Reregistration Eligibility Decisions (IREDs), Biopesticide Registration Action Documents (BRADs), Registration Review Decisions, Registration Review Interim Decisions.

D. Labeling Changes by Notification

PR Notice 98-10 sets forth what actions can be done through notification and non-notification. Some of these changes can be made simply by "Notification"; which generally involves an Application for Pesticide Registration/Amendment form (EPA Form 8570-1) marked "Notification", a copy of the labeling with changes highlighted, and a certified statement of the notification, submitted to the Document Processing Desk. *PR Notice 98-10*. Notifications are processed separately from amendments. The Agency will respond in writing as it is able to do so. If the "notification" documents raise a concern with the label reviewer, he or she may require the registrant to submit an application for amendment when necessary. *40 CFR 152.46(a)(2)*. The following modifications are some that can be made by notification. Refer to
PR Notice 98-10 for specific information on the circumstances under which the Agency has determined notification is appropriate and for additional topics that can be modified through notification.

- Adding or changing alternate brand names
- Changing primary product name
- Adding or deleting pests (exceptions include, but are not limited to, pests of public health significance, termites or pests under USDA quarantine)
- Adding indoor, nonfood sites to antimicrobial products
- Changes in packaging and related labeling statements
- Use deletions related to Data Call-Ins
- Storage and disposal statements
- Use of symbols and graphics (except Skull & Crossbones)

- Changes in Warranty Statements
- Addition of certain relevant information to the labeling of an antimicrobial pesticide product regarding product efficacy, product composition, container composition or design, or other characteristics that do not relate to a pesticidal claim or pesticidal activity (see *FIFRA § 3(c)(9)*)

Please note that registrants may no longer add or change advisory label statements by notification. (See *PR Notice 2000-5*). Please also note that there is a separate process for antimicrobials (*See FIFRA 3(h)(3)(f)*).

E. Amendments

1. No Data Review Required

   This type of submission involves an application for an amendment to a currently registered pesticide where no data is required for review of the action. An example is an amendment for the addition to the label of a new site or pest, which has been previously approved by the Agency for other products containing the same active ingredient. For products composed of multiple active ingredients, the proposed new site must be previously approved for all of the a.i.'s. For certain pests, such as public health pests, quarantine pests, and structural pests, data are required to demonstrate efficacy.

2. Data Review Required

   This type of submission involves an application for amendment of a currently registered pesticide where the request involves the need to review data. For example, the request may involve a new use, a new application rate, or a change in precautionary statements. A data review is also required to be expanded when there is a new public health claim (such as control of a human pathogen or control of mosquitoes) or when the environmental or human exposures are changed (e.g., a residential assessment is needed when turf/lawns are added to a label that has sod grass as a use site). This is an action not previously approved by the Agency, and a data submission and review is necessary. Review of the label will be based upon the conclusions of the data reviews. Generally, the specific reviews will only affect a small portion of the label; the rest of the text should remain unchanged from the originally accepted label.

F. Identical or Substantially Similar Products

For identical or substantially similar product (formerly known as "me-too") submissions, the pesticide product and the proposed use must be identical or substantially similar to a currently registered pesticide or may differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. *FIFRA 3(c)(7)(A)*. Identical or substantially similar products may be a "repack", if the product is manufactured by simply repackaging from another registered product, with no changes to its composition. As a "repack," a product may not include use sites that are merely similar to use sites on the

label of the product being repackaged. For example, if the product being repackaged includes directions for use on commercial apple orchards, it would not be acceptable for the new product to include directions for use on apple trees in residential areas. The sites must be the same. The label does not necessarily have to have all the uses but the repacked product cannot have more uses on the label than the product from which it is repacked.

The applicant must cite the currently registered pesticide product by EPA registration number. The Agency must first ensure that the two products *are* substantially similar or identical in formulation before the label review can begin.

The label reviewer must also ensure that the new product's use patterns, including any public health claims, are the same as those of the cited product. In addition, if the label under review is a rodenticide, repellent, or antimicrobial bearing a public health claim, any changes in the other intentionally added ingredients must be cleared by the efficacy reviewers to make certain that these changes will not affect the efficacy of the product (i.e., change of bait color, smell, texture, etc.) No changes to the composition of the rodenticide baits or repellents may be accepted without an efficacy review.

G. Products for Which Efficacy Data Must Be Submitted

Efficacy studies document how well pesticide products perform as pest control agents. These studies may include tests to determine the lethality of a formulation against a certain pest species, to document effectiveness under actual use situations, and/or to determine whether claims beyond mere control are supported (i.e., length of a residual effect).

Although the Agency routinely waives the submission (but not the requirement to conduct the study) of efficacy data for most products (except for the types of products listed below), the applicant or registrant is required to have such data on file for each product. EPA reserves the request that the data be submitted at any time, either during initial review or subsequent to registration. The reviewer should be alert to label claims that seem to promise control or performance beyond that of similar products. Examples of products with such claims include herbicides that claim control of weeds in lawns for one full year, and cotton insecticides that claims total season-long elimination of pink bollworm with just one application. When a reviewer identifies questionable or unusual efficacy claims, the PM/team leader should be consulted and, if warranted, the applicant should be told to delete the claims or to submit efficacy data that support the claims. If the reviewer is not sure whether proposed claims are appropriate, the submission should be routed to an efficacy reviewer for assessment.

1. Some Types of Products Requiring Submission of Efficacy Data

a. **Antimicrobials.** Pesticide products intended to control microorganisms infectious to humans or animals.

b. **Invertebrate Control.** Products intended for use in or on humans (or in or on pets for control of pests which attack humans such as fleas, ticks, mosquitoes, and biting flies) and in premises or in the environment to control pests of sanitary or public

health significance such as those above as well as termites, wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes, and bedbugs. See *PR Notice 96-7* for important information on termiticide labeling and efficacy data requirements for termiticides.

c. **Rodenticides and Repellents.** Rat and mouse control products; products used to disperse or control birds that pose health threats; products used to control rabies vectors such as bats, skunks, raccoons, foxes, coyotes; products used to control rodents considered to be disease vectors; and products used to control vertebrate animals such as poisonous snakes, dogs, and bears that can injure humans by direct attacks.

d. **New Actives Ingredients with Public Health Uses or New Public Health Uses.** Formulated products that either contain new active ingredients or have proposed use patterns that differ from any previously accepted for a similar formulation, and that have public health uses.

e. **Products to Control Mycotoxin-Producing Organisms.** Products intended to control organisms that produce mycotoxins (organic compounds produced by the fungi which may be highly toxic and carcinogenic to mammals).

2. **Product Team Structures/Roles Regarding Efficacy Data**

Within the Office of Pesticide Programs, product performance (efficacy) data are specific to and evaluated by the three product Divisions: Antimicrobial Division (AD), Registration Division (RD), and Biopesticides and Pollution Prevention Division (BPPD).

The Antimicrobial Division has developed guidance documents called DIS/TSS enclosures for the review of antimicrobial pesticides, including determination of health-related and non-health-related issues and label requirements. Efficacy issues including label review are handled by the Product Science Branch in the Antimicrobial Division. The microbiologists within this branch are responsible for determining whether the product claims are supported by the data and that the directions for use are appropriate for the claims.

Within the Fungicide and Herbicide Branches in RD, submission of efficacy data are generally not required since the target pests seldom affect human health. Because efficacy data is necessary for registration of certain insecticides and rodenticides, technical reviewers within the Insecticide-Rodenticide Branch review the product performance data submitted with these products.

Within the Biopesticides and Pollution Prevention Division (BPPD) science reviewers evaluate efficacy and may consult other efficacy reviewers in other parts of OPP as needed.

H. Special Local Needs (SLN)

States have authority under *FIFRA Section 24(c)* to register additional uses for a federally registered pesticide. Such registrations are for distribution and use only within a particular state to meet a "Special Local Need" ("SLN"). Although SLNs can be approved for many different reasons and application sites, most involve use on crops. A certain crop grown within a state may be attacked by a new pest not on a current label, or state officials may expect it to be attacked sometime during the growing season, thereby creating a special pest problem. The pesticide ingredients must have an established tolerance associated with the crop, or be exempted from the requirement of a tolerance for that crop. *FIFRA 24(c)(3).* Although most 24(c) registrations consist of adding a use to a federally registered product, the state may also register a new end-use product (not federally registered) as a 24(c) registration with a stand-alone label. See *40 CFR 162.152(b)(2)* for information on the types of new end-use products for which a state may issue a 24(c) registration.

SLN registrations are effective unless EPA takes action to disapprove such registrations. If the Agency determines the SLN must be disapproved, EPA must provide notice of the disapproval, in writing, to the state within 90 days of the effective date of the registration. See disapproval process at *40 CFR 162.154.* SLN registrations that are issued without following the procedures laid out in 40 CFR 162.152 may be invalidated by the Agency. *40 CFR 162.156(a)(3).* In such cases, EPA will attempt to provide this information to the state no later than 90 days from the effective date of the registration.

Special Local Need labels are not stamped "Accepted", but are reviewed for the required, pertinent information. EPA sends the State an acknowledgement letter. If there is a problem with the SLN (e.g., no established tolerance), a notice of intent to disapprove or invalidate, if appropriate, is sent to the State by the PM/team leader. If something is omitted from the label, the State is informed; however, the SLN is not disapproved. Occasionally, it is necessary to send the SLN for science review depending on the use pattern.

The Section 24(c) review process is described in further detail in OPP's Standard Operating Procedure #4007.1, February 9, 1996.

I. Experimental Use Permits

Experimental Use Permits (EUP) authorize testing (such as greater than ten acres terrestrial; one acre aquatic; or on a case-by-case basis as EPA determines that an EUP is required) of unregistered pesticides or registered pesticides unregistered use. See *40 CFR 172.3* for a description of the types of tests that generally require a permit. The EUP label follows the standard label format, except that the label must also include:

- The EPA Experimental Use Permit No. *40 CFR 172.6(a)(2).*
- The statement: *"Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use program", 40 CFR 172.6(a)(3).*
- The statement *"For Experimental Use Only". 40 CFR 172.6(a)(1).*

- The name and address of the permittee, producer or registrant. *40 CFR 172.6(a)(5).*

Refer to *40 CFR 172.6* for additional labeling requirements. EUP's are usually issued for a period of one year for a specific number of pounds to be used on a specific acreage, but may be extended for longer periods. *40 CFR 172.5*.

J. Re-registration

The 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorized EPA to conduct a comprehensive pesticide reregistration program in order to completely review the human health and environmental effects of pesticides first registered before November 1, 1984, and make decisions about these pesticides' future use. The goal of the reregistration program is to mitigate risks associated with the use of older pesticides while preserving their benefits. Pesticides that meet current scientific and regulatory standards may be declared "eligible" for reregistration. The results of EPA's reviews are summarized in Reregistration Eligibility Decision (RED) documents. Products undergoing reregistration receive a product-specific data call-in (PDCI) that requires product chemistry and acute toxicity data on that product. Compliance with RED label changes is required during reregistration, and companies have to submit copies of labels with the changes required in the RED with the PDCI responses for review.

IV. When a use is deleted

Use deletions are published in the Federal Register according to the requirements of *FIFRA 6(f)(1)(B)*. When a use is voluntarily deleted from the label, the label is not stamped accepted even if it is found to be acceptable upon review until the use cancellation FR notice comment period has concluded with no substantial comments. Registrants that intend to delete uses must submit a request to voluntarily terminate the use as described in section 6(f)(1) of FIFRA, an application for amended registration and five copies of revised labeling requesting the deletion of uses. See *40 CFR 152.44* and *152.50*. Two copies of a marked-up version of the previously approved labeling highlighting the deletions should be included.

Revised May 2012

Label Review Manual

Chapter 5: Ingredient Statement

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Elizabeth A. Sellers

I. Introduction

This chapter covers the ingredient statement and footnotes sections of the label, which must contain, as provided in *40 CFR 156.10(g)* the name and percentage by weight of each active ingredient, the total percentages by weight of all "Other Ingredients" and sub statements including, but not limited to: the acid equivalent, elemental equivalent, toxic ingredients, petroleum distillates, sodium nitrite, and corrosivity.

Format

The label must have a clear and prominent ingredient statement that contains the name and the percentage of each active ingredient, and the total percentage of all "inert" or "other" ingredients, in the pesticide. The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text. See *40 CFR 156.10(a)(2)*. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" must not be used as a heading for the ingredient statement. *40 CFR 156.10(g)(1)*

II. What is included in an ingredient statement

A. Contents

The name and nominal concentration expressed as a percentage by weight of each pure active ingredient must be placed under the ACTIVE INGREDIENT heading and the total percentage by weight of all inert/other ingredients must be placed under the heading INERT INGREDIENT or OTHER INGREDIENT (or plural forms of these terms when appropriate).

1. **Headings.** The headings "ACTIVE INGREDIENT" and "OTHER (INERT) INGREDIENT" (or plural forms of these terms when appropriate), must be the same type size, aligned to the same margin and equally prominent. PR Notice 97-6 recommends "OTHER INGREDIENT" instead of "INERT INGREDIENT", but either may be used. Additional formatting requirements are set out at *156.10(g)(2)(ii)*, which provides that the "text of the ingredient statement run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text".

2. **Percentages.** The percentages shall be stated in terms of weight-to-weight and the sum of percentages of active and inert ingredients shall be 100. Percentages shall not be expressed by a range of values as 22–25%. *40 CFR 152.10(g)(4)*. The percentages of active and other ingredients should be aligned by the decimal point.

B. Active Ingredient

Under *40 CFR 152.3*, active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of FIFRA section 2(a), except as provided in *40 CFR 174.3*.

C. Other Ingredient (Inert)

Under *40 CFR 152.3*, inert ingredient means any substance (or group of structurally similar substances if designated by the Agency) other than an active ingredient, which is intentionally included in a pesticide product, except as provided by *40 CFR 174.3*, as it relates to Plant-Incorporated Protectants. Some examples of ingredients that may be inert ingredients include: solvents, stabilizers, spreaders or stickers, preservatives, surfactants, defoamers, etc.

PR Notice 97-6 sets forth the Agency's policy concerning the use of "inert" on the label ingredients statement. Under this policy, applicants and registrants are permitted to substitute the heading "Other ingredients" for the heading "Inert ingredients."

III. Location of ingredient statement

A. Front Panel

The ingredient statement is normally required to appear on the front panel of the label, preferably immediately below the product name, unless doing so is impracticable and the Agency grants permission to place it elsewhere. *40 CFR 156.10(g)(2)(i)*. (Refer to the sample label formats in chapter 3.) Some examples might be if the pesticide package is extremely small or irregular in shape to the point of making it difficult to place the ingredient statement on the front panel of the label. In such cases, permission may be granted, upon written request (as part of the application), for the ingredient statement to appear on the back or side panel of the label.

B. For Outside Containers/Wrappers

If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper. *40 CFR 156.10(g)(2)(i)*.

IV. Names to be used in the ingredient statement

The label reviewer must review the names for ingredients used on the proposed label and cross-reference the names in the OPPIN database on the LAN. If none of the names are included in OPPIN, perhaps the chemical name of the active ingredient is new or the registrant used an

inappropriate name. If so, check with your PM/team leader for the correct procedures to follow. Look at each section below to determine the correct names to be used in the ingredient statement.

A. Common Name

The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. *40 CFR 156.10 (g)(3)*. Through PR Notice 97-5, the Agency clarified what it considers as acceptable common names. EPA will permit the use of common names approved by the American National Standards Institute (ANSI) in the label ingredients statement without the accompanying scientific chemical names, and will permit the use of other common names listed in *PR Notice 97-5* without the accompanying scientific chemical name. When a common name only appears on the label, EPA also recommends the inclusion on labels of Chemical Abstracts Service (CAS) numbers to identify ingredients definitively. See section C, below for further information.

The label reviewer should check OPPIN to determine the accepted common name. "(ANSI)" or a "C" in the TYPE column will be shown with the accepted common name in the Chemical Name list. An additional source for this information on older chemicals is the EPA publication, *Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels*, 4th edition (December 1979).

An alphabetical listing that contains some of the common/chemical names may also be found in the *Alphabetical Listing of Pesticide Chemicals* at the beginning of *40 CFR Part 180.* Because this list only includes names for ingredients with tolerances, it is only a secondary source. Similarly, a list of some common/chemical names can be found in *PR Notice 97-5*.

B. Chemical Name

If the active ingredient has a common name, but not one that is considered "**accepted**" the full chemical name must be used in conjunction with a common name *40 CFR 156.10(g)(3)*. For example:

Acephate (0,S-dimethyl acetylphosphoramidothioate)

EPA requests that chemical names be consistent with the nomenclature used in the Chemical Abstracts (CA) Chemical Substance Index, published by the American Chemical Society. OPPIN reflects the correct chemical name: the entry found with the "9CI" (i.e., Ninth Collective Index) designation at the end of the name. (*OPPIN tip for label reviews:* hit the Enter key on the chemical name to see the complete chemical name, which may not appear on the line if the name is too long to fit on the line.)

C. CAS (Chemical Abstracts Service) Number

The CAS number for the active ingredient(s) may be used on the label in connection with the ingredient statement. If the CAS number is used, it should appear as a sub-statement (footnote) to the ingredient statement and not in any way detract from the ingredient statement.

D. Microbial Name

If the active ingredient is a microbial agent, the Agency prefers that the microbial agent be identified by genus and species (and if appropriate also by subspecies and/or isolate number). Again, this name should be identical to the name shown in OPPIN.

E. Descriptive Name

Descriptive names approved by the Agency may be used in the ingredient statement if there is no accepted common name and no distinctive chemical name. Examples are: "Tobacco dust", "Egg solids", or "Dried blood". Approved descriptive names are listed in OPPIN, and the name shown on the proposed label must be identical to the name found in OPPIN.

F. Trademark Name

A trademark or proprietary name may not be used in the ingredient statement unless it has been accepted as a common name by the Administrator under the authority of *FIFRA Section 25(c)(6). 40 CFR 156.10(g)(3).*

V. Criteria for determination of pesticidal activity

A. Is the Ingredient Considered to Be Active?

The criteria for determination of an ingredient's active or inert status are located in *40 CFR 153.125*. Generally speaking an ingredient will be considered an active ingredient if, by itself, and when used as directed at the proposed use dilutions, it has the capacity to function as a pesticide or has the ability to elicit or enhance the effect of another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Ingredients such as stickers and other adjuvants which function simply to enhance or prolong the activity of an active ingredient by physical action are not generally considered to be active ingredients.

A chemical may be an active ingredient in one formulation and an inert ingredient in another. Examples are chemicals used as preservatives of a formulation, plant nutrients, or chemicals with some other non-pesticidal use.

B. Active Related Compounds

As described in *PR Notice 81-4*, EPA recommends that related compounds that are now distinguishable from the intended active ingredient(s) due to newer, more discriminating methods of analysis must be accounted for within the pesticide label ingredients statement. If one or more related compounds is isolated and found to have pesticidal activity to the target pest, EPA requests that it be specifically identified and quantified by percentage under the ACTIVE INGREDIENT heading of the label ingredients statement. For example:

ACTIVE INGREDIENTS:	
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, α isomer	20.0%
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, β isomer	3.0%
OTHER INGREDIENTS	77.0%
Total	100.0%

C. Inert Related Compounds

Related compounds whose active/inert status is not determined by the registrant, must be included (without designation as related compounds or by name) under the total percentage of the INERT INGREDIENT or OTHER INGREDIENT heading (see *PR Notice 81-4*).

D. Equivalents:

Unless declared as an active ingredient, a related compound must not be included in expressing percent acid or metallic equivalents, nor in the declaration of "pounds active ingredient" or "acid (or metallic) equivalents per gallon" under the ingredient statement. (*PR Notice 81-4*).

VI. Statement of concentrations

A. Definition

The percent nominal concentration specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in *40 CFR 158.130(2)*. The nominal concentration is the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight. The nominal concentration is the *only acceptable method for expressing* the percentage of active ingredient in the product. **All pesticide ingredient statements must be expressed as nominal concentration.** See *40 CFR 158.320.*

B. Expressions of Ingredients

1. The percent of the pure active ingredient in a technical grade product is the same as its nominal concentration. This must be indicated in Columns 10 and 13b of the CSF.
2. The nominal concentration in a formulated product is a function of the percentage by weight of the active ingredient in the product (including associated ingredients) and the purity of the source product (its nominal concentration). For example:

   If the purity of the active source is 80%, as declared in column 10 of the CSF, and the percentage by weight of the active ingredient in the formulated product is 20% as indicated in column 13(b) of the CSF, the nominal concentration of the product would be 16% (20% x 0.80), consistent with the label claim. The 16% nominal concentration can be indicated between parentheses in the same column below the 20% w/w.

3. If wider limits for active and inert ingredients were justified as per the regulations *40 CFR 158.350*, the proposed upper and lower certified limits must be indicated on the Confidential Statement of Formula (CSF) and the guarantee of each active ingredient in percent must be indicated on the label. The guarantee ingredient statement on the label is the nominal concentration, which must be a value between the upper and lower certified limits, not equal to either value.
4. The sum of the percentage by weight of the active ingredient and intentionally added inert/other ingredients in a formulated product must equal 100%. *40 CFR 156.10(g)(4)*.
5. For ingredient statements which reflect the fact that the active ingredient is the only component of the product, the inert ingredients header is not necessary. For example, for a product which is 100% pure chlorine gas, the following ingredient statement is acceptable, per *40 CFR 156.10(g)(1)*:

   ACTIVE INGREDIENT:

Chlorine	100.0%

   Assuming that the chlorine gas is only 99% pure, then the following ingredient statement would be required:

   ACTIVE INGREDIENT:

Chlorine	99.0%
OTHER INGREDIENTS	1.0%
Total	100.0%

6. If the proposed label is for a liquid formulation, the label reviewer must check the Directions For Use section. If any of the use directions of the pesticide product are expressed as a certain weight of active ingredient per unit area (such as pounds per

acre), a statement of the weight of the active ingredient per unit volume of the pesticide formulation must also appear at the end of the ingredient statement. *40 CFR 156.10(g)(4)* This is very important when calculating the use rates. An example of this would be, "One gallon contains 4 pounds of the active ingredient (chemical)". If dosage rates in the directions for use are expressed as weight of product/unit area, the weight of the product/gallon must be stated.

VII. Substatements for Certain Inert/Other Ingredients

Based on historical practice, EPA prefers the following footnotes appear on the label, as applicable:

A. Petroleum Distillates

Products containing petroleum distillates, xylene or xylene range aromatic solvents at ≥10% should be indicated on the label immediately below the ingredient statement as a footnote below the term "Inert ingredients" or "Other Ingredients" as follows:

"Contains petroleum distillates, xylene or xylene range aromatic solvents".

B. Sodium Nitrite

EPA has historically required, based on *40 CFR 156.78(a),* that products containing >0.1% sodium nitrite add the following statement to the ingredients statement:

"This product contains sodium nitrite".

VIII. Deterioration

A. Required Statement

In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear the following statement in a prominent position on the label:

"Not for sale or use after (date)".

40 CFR 156.10(g)(6)(i). Note the product must meet all label claims up to the expiration time indicated on the label.

B. Sodium Hypochlorite.

For sodium hypochlorite products containing 5.25–12.5% active ingredient, the Agency historic practice has been that instead of an expiration date on the label, the following

labeling statement is necessary to ensure the product is effective (because of its rapid degradation). See PRN 70-16.

"Degrades with age and exposure to sunlight and heat. Use a test kit and increase dosage as necessary to obtain the required level of available chlorine".

IX. Specific designations for some ingredient statements

Some pesticide ingredients need specific designations on the ingredient statement for proper clarification and identification. Examples of some of these specific designations are shown below:

A. Microbial Pesticides

Biopesticides are generally subject to the same labeling provisions as conventional pesticides. They are viewed essentially the same as chemical pesticides with respect to label requirements, except for differences with the ingredient statement.

1. Viability. For products containing live microorganisms, the agency has historically required that the label indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight or volume of product. The OPPTS Harmonized Test Guidelines, *Series 885 Microbial Pesticide Test Guidelines* address this topic. Certified limits can be expressed as:

   (a) Microbial Pest Control Agents (MPCA) units/unit weight or volume

   (b) International Units of Potency per unit weight

   (c) Weight percent of product

   Items (a) and (b) may be expressed using biological, genetic, biochemical, serological or other appropriate data. For example:

ACTIVE INGREDIENT:	
Pseudomonas syringae strain ESC-10	3.8% (by wt.)
OTHER INGREDIENTS	96.2% (by wt.)
Total	100.0% (by wt.)

Contains at least 50 million viable cells/lb (10^5 cells/gram).

ACTIVE INGREDIENTS:	
Trichoderma harzianum (ATCC 20476)*	16.6% W/W
Trichoderma polysporum (ATCC 20475)**	16.6% W/W

OTHER INGREDIENTS	66.8.% W/W
Total	100.0% W/W

* Contains a Minimum of 4.5 million colony forming units (CFU) per pound (454 grams)

** Contains a Minimum of 14 thousand colony forming units (CFU) per pound (454 grams)

2. For *Bacillus thuringiensis* (Bt) products, the percentage of active ingredient for the ingredient statement will be calculated using the dry weight of the fermentor solids and solubles, including the spores and toxins as the amount of the active ingredient. For liquid products, a representative sample of the technical material is to be dried down to determine the dry weight for the purpose of expressing the percentage of active ingredient on the label. The weight of the water is to be included in the inert ingredient percentage on the label. Strain variety must appear on the label. (*PR Notice 72-6*). The use of potency units expressed in terms of International Units (IU) per milligram of product is not allowed except when standards are obtained from an EPA-recognized international authority. Instead of International Units, company-maintained target insect assay units are acceptable when named after the insect. (e.g. "cabbage looper units") If potency units are used, the designation should appear on the label immediately below the ingredient statement and should be followed by the statement *"the % active ingredient does not indicate product performance and potency measurements are not federally standardized*". For example:

ACTIVE INGREDIENTS:	
Bacillus thuringiensis subspecies *kurstaki* strain AB1*	.5.0% w/w
OTHER INGREDIENTS	95.0% w/w
Total	100.0% w/w

* Potency: 10,000 cabbage looper units per mg of product or 4540 cabbage looper units per a pound of product
The % active ingredient does not indicate product performance and potency measurements are not federally standardized

B. Biochemical Pesticides

The ingredients statement for a product for which the active ingredient is a naturally occurring plant regulator, (such as cytokinins, auxins, or gibberellins) and for which quantitative chemical methods and units are not available, should be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENT:	
Cytokinin*	3.0%
OTHER INGREDIENTS	97.0%
Total	100.0%

*equivalent to 200 ppm kinetin activity

C. Pheromone Products

The ingredient statement for pheromone dispenser labels shows the pheromone in mg. per dispenser as a footnote. This must be as reflected in the CSF.

ACTIVE INGREDIENT:	
Pheromone*	1.0%
OTHER INGREDIENTS	99.0%
Total	100.0%

*x mg per dispenser

D. Insect Virus-based Insecticides

Pesticide products containing an insect virus as the active pesticide ingredient must indicate the number of activity units (polyhedral inclusion bodies for nuclear polyhedrosis viruses or capsules for granulosis viruses) per gram (10^6 PIBS/gm) or percentages (%). For example:

ACTIVE INGREDIENT*:	
Polyhedral Inclusion Bodies of Douglas Fir	
Tussock Moth Nuclear Polyhedrosis Virus	13.5%
OTHER INGREDIENTS	86.5%
Total	100.0%

*Contains at least 70 million activity units per gram.

Often the active ingredient statement will include "... and insect body parts..." whether the baculovirus is propagated in vivo or in vitro. For example:

ACTIVE INGREDIENTS:	
Granulosis Virus of Cydia Pomonella (Coddling Moth)	
(at least 5 x 108 GIBS/ml)	0.005%
OTHER INGREDIENTS	99.995%

Insect parts/water/inert solids	99.985%
Aureomycin (5.5%)	0.015%
Total	100.000%

E. Salts, Amine or Ester of Acids

If the active ingredient is a salt, amine or ester of an acid, the label should declare in a substatement under the ingredient statement the percentage equivalent of the acid. For example:

ACTIVE INGREDIENTS:	
Isooctyl ester of 2,4-Dichlorophenoxyacetic acid*	12.0%
Isooctyl ester of 2-(2,4-Dichlorophenoxy) propionic acid**	10.0%
OTHER INGREDIENTS:	78.0%
Total	100.0%

* 2,4-Dichlorophenoxyacetic acid equivalent, 9.5%

** 2-(2,4-Dichlorophenoxy)propionic acid equivalent, 9%

F. Metal Salts or Complexes

Pesticide products for which the active ingredients are readily soluble metal salts or complexes (e.g., copper, zinc, manganese, magnesium, iron) should declare the chemical name of the metalcomplex as active ingredient and the equivalent metallic elementdeclared in a substatement. For example:

ACTIVE INGREDIENT:	
Copper naphthenate*	93.2%
OTHER INGREDIENTS:	6.8%
Total	100.0%

*Metallic copper equivalent, 22%

G. Halide Compounds

Certain halide compounds (e.g., bromine, chlorine, iodine) have historically been required to have a reference in the ingredient statement to the available halide in water. Such a reference is applicable when a halide product's directions for use specify that a certain concentration of the halide (e.g., ppm free chlorine) be achieved in water by dilution or by testing. An example of the ingredient statement follows:

ACTIVE INGREDIENT:	
1-Bromo-3-chloro-5,5-dimethylhydantoin	86.4%
1-3 dibromo-5,5-dimethylhydantoin	8.6%
OTHER INGREDIENTS:	5.0%
Total	100.0%
Provides:	66.8% Available Bromine 25.4% Available Chlorine

H. Metal Ion Exchange Resins:

Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, should be declared on the label as the percent metallic equivalent with a footnote immediately below the ingredient statement specifying the identity and amount of the ion exchange resin which was used.

I. Sodium Chlorate Products:

Because sodium chlorate is extremely flammable, all pesticide products containing sodium chlorate should include a fire retardant in the formulation. These labels must bear in the vicinity of the ingredient statement, a statement indicating that the product contains a fire retardant. If the proposed label is a sodium chlorate product, check the CSF to verify that the product contains a fire retardant (column 15, Purpose in Formulation).

J. Arsenic Containing Products:

Pesticide products which contain arsenic in any form should include a substatement of the percentages of total arsenic and water-soluble arsenic calculated as elemental arsenic. See *40 CFR 156.10(g)(1)*. For example:

"Total arsenic, all in water soluble form, expressed as elemental' xx%"

K. Fertilizer-pesticide Combinations:

Pesticides that are formulated in combination with fertilizers bear an ingredient statement the same as any other pesticide. The fertilizer composition is shown separately from the pesticide ingredient statement and may not detract from or obscure the required pesticide labeling statements.

L. Complexing Agents:

In products containing an active ingredient bound with other agents as a complex, the active ingredient should be declared in the ingredient statement with a footnote immediately below the active ingredient statement listing the complex formed. In the case of complexed iodine, for example, the active ingredient is titratable iodine.

ACTIVE INGREDIENT:	
Iodine*	15.0%
OTHER INGREDIENTS	85.0%
Total	100.0%

*from (name of complexing agent)

X. Inert ingredients

Pesticide products with food use sites do not contain List 1 inerts. Reviewers need to ensure that food use products only contain inert ingredients that have a tolerance or tolerance exemption and that any limitations on the use of the inert ingredients are followed. See *40 CFR 180*.

A. Special Labeling Requirements for Inerts of Toxicological Concern (List 1)

Products containing one or more other/inert ingredients on List 1 (inert ingredients of toxicological concern) have historically been required to include on the label the statement: "This product contains the toxic inert ingredient (name of inert)". See Inert Ingredients in Pesticide Products; Policy Statement *OPP-36140; FRL-3190*; *40 CFR 156.10(g)(7)*. This statement must be placed in close proximity to the ingredient statement in a type size comparable to other front panel text. For enforcement purposes applicants have been asked to indicate on the label the "maximum" percent of ingredients of toxicological concern characterized in the product. *PR Notice 90-1*, issued May 1, 1990, announced the revision and modification of previous published lists of inert ingredients in pesticide products that are of toxicological concern and require priority testing. In general, after the PR Notice was issued EPA has not registered any new products containing a List 1 inert. EPA's inert list is available on the Web: *Inert Ingredients in Pesticide Products | Office of Pesticide Programs | US EPA*.

B. Listing of Inert/Other Ingredients

Inert ingredients are not required to be identified individually in the ingredient statement except when EPA determines that such inert ingredient may pose a hazard to man or the environment. See *40 CFR 156.10(g)(7)*. In such a situation, EPA may require that the name of the inert be listed in the ingredient statement. However, if a registrant wants to list a particular inert ingredient in the ingredient statement, the registrant should list **all** inert ingredients directly below the ingredient statement in descending order by weight. A partial listing on the label could be misleading.

Registrants are encouraged to disclose on the label the inert/other ingredients in their pesticide product either by chemical name or functional category with a brief explanatory definition. For example:

Other Ingredients	92.8%
monochlorobenzene, glycerin, 8-hydroxyquinoline sulfate and dimethylpolysiloxane	
Other Ingredients	92.8%
Diluent, emulsifier, defoamer, preservatives and stabilizer	

XI. Alternate formulations

EPA may approve a basic formulation and one or more alternate formulations for a single product. An alternate formulation must meet the criteria listed in *40 CFR 152.43(b)(1) through (4)*. The Agency may require the submission of data to determine whether the criteria have been met. Registrants are encouraged to keep their alternate formulas, if any, up-to-date. The label text of the alternate formulation product must be identical to that of the basic formulation. *40 CFR 152.43(b)(3)*. The Agency will not approve an alternate formulation if the alternate formulation requires a change in the label text.

The alternate formulation must have the same certified limits for each active ingredient as the basic formulation. *40 CFR 152.43(b)(1)*. If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation. *40 CFR 152.43(b)(2)*.

The analytical method required under *40 CFR 158.355* must be suitable for use on both the basic formulation and the alternate formulation.

Alternate formulas, should be clearly marked "Alternate Formula A", "Alternate B", etc. Further, indication that an alternate formula is replacing "alternate formula x" or is in addition to "alternate formula y" would reduce confusion.

Except for approved dye substitutions, EPA does not generally accept alternate formulations for rodenticides.

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Label Review Manual

Chapter 6: Use Classification

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I. Introduction

End-use pesticide products (as opposed to products solely for further formulation into other pesticides) (See *40 CFR 152.166*) may be classified as Restricted Use Pesticides (RUP), or general use, or may be unclassified. *40 CFR 152.160(a)*. The Agency does not normally classify products for general use; products that are not restricted remain unclassified. *40 CFR 152.160(a)*. If the Agency determines that the pesticide, when applied in accordance with the label's directions for use, warning and cautions, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. *FIFRA 3(D)(1)(c)*.

It is the Agency's policy that when labeling cannot sufficiently mitigate the risk, special training in handling and applying the pesticide product is necessary to ensure the safe use of the product. The sale and distribution of RUPs must meet the regulations set out at *40 CFR 152.167*, or those restrictions established through Agency regulation. *FIFRA 3(d)(1)(C)(i)&(ii)*. The use of RUPs is limited to certified applicators or persons under their direct supervision. *FIFRA 3(d)(1)(C)(i)&(ii)*; *40 CFR 152.175*. Users of unclassified products are not limited in any manner unless the labeling limits use to a specific definable group, (e.g., veterinarians). See *Chapter 11* for further explanation of this issue.

II. Unclassified products

A. Criteria

If the label under review meets any of the criteria below, then the product may remain unclassified.

1. **Identical or Substantially Similar.** The product under review is an identical or substantially similar registration, and the product cited as substantially similar is unclassified.

2. **Data Supported.** The product under review is a new product for which data were submitted and none of the following data reviews indicates that the product should be considered for restricted-use classification.

   (a) Environmental Effects, Fate and Groundwater reviews assess the toxicity to fish, birds and mammals, and endangered species and assess the possibility of groundwater contamination and persistence in soil.

   (b) Chemistry and Exposure reviews assess the degree of human health exposure.

   (c) Toxicity reviews assess the acute and chronic toxicity of the product, and the acute and chronic human health hazards.

(d) Note that under *40 CFR 152.170(d)*, there may be other evidence such as field studies or monitoring data that would result in the Agency determining that a pesticide should be restricted use.

3. **Manufacturing Use Products.** The product under review is a manufacturing use product (MP). MPs are not subject to the *40 CFR 152.166* restricted use labeling requirements.

4. **Active Ingredients Have not Previously Been Classified Restricted Use.** The product under review contains no active ingredient(s) or use(s) which have been previously classified as restricted use. To check: Refer to *40 CFR 152.175*. Another reference source for this information is the Webpage: *http://www.epa.gov/opprd001/rup/*.

If the label under review does not meet one of the above criteria, then the product may be classified as an RUP.

III. Restricted use pesticides (RUP)

A. Determination of Classification.

Review the criteria below to determine whether the product should be classified as an RUP.

1. If the product under review is an identical or substantially similar registration and the cited product is classified as an RUP, then the product label under review must bear the Restricted Use classification. Go to section B below on *"Labeling Requirements for RUPs"*.

2. Based on a review of the data that support the product registration, the pesticide may be classified as RUP if its toxicity exceeds the specific hazard criteria set out at *40 CFR 152.170*. Even if the RUP criteria are triggered, the Agency must determine if the potential risk can be adequately mitigated through additional labeling restrictions. The label reviewer should check with the Product Manager/team leader to determine if this is the case. See *40 CFR 152.170(e)*. If not, the product must be classified as an RUP. Go to Section B. below on *"Labeling Requirements for RUPs"*.

MITIGATION OPTION: If the PM/team leader determines that the product should not be classified as an RUP because additional label language can mitigate the risk, then the label reviewer must include a memo to the file noting this decision. The memo must specify the basis for the decision under *40 CFR 152.170(e)*, including the alternative labeling language required. The label reviewer must sign and date the memo, place it in the registration jacket, and ensure the product label under review does not bear any use classification.

B. Labeling Requirements for RUPs.

Restricted use pesticides are subject to the labeling requirements specified in *40 CFR Part 156*, including the requirements set out in *40 CFR 156.10(j)(2)* described further in *PR Notice 93-1*. The product may have both general and restricted uses. If there is a restricted use, the labeling requirements for restricted use must be followed. Check the label under review to make certain that the label meets the RUP labeling requirements listed below:

1. The statement "Restricted Use Pesticide" must appear at the very top of the label's front panel. *40 CFR 156.10(j)(2)(i)(A)*. No other wording or symbols should appear above the RUP statement. *PR Notice 93-1*. The phrase "Restricted Use Pesticide" on the front panel must meet the minimum type size requirements of the human hazard signal words. *40 CFR 156.10(j)(2)(i)(A)*. If type size is too small, the label reviewer must notify the registrant in writing of the type size requirements specified in the Code of Federal Regulations at *40 CFR 156.60(b)(1)* for the signal word.

2. A briefly stated reason for the restricted use classification should directly follow "Restricted Use Pesticide". *PR Notice 93-1*.

3. A summary statement of the terms of the restrictions must follow. *40 CFR 156.10(j)(2)(i)(B)*. (See the next section below for examples of chemical-specific RUP statements and reasons for RUP classification).

4. The RUP statement should be enclosed in a box to enhance its visibility on the label. *PR Notice 93-1*.

5. The RUP statement must appear with sufficient prominence in relation to other label text and graphics so as not to be overlooked. *40 CFR 156.10(j)(2)(i)(A)*.

6. The label must bear the phrase "Restricted Use Pesticide" under the heading "Directions for Use". *40 CFR 156.10(i)(2)(i)*.

7. The label must not bear any designation indicating that certain uses are restricted and other uses are not restricted. If the registrant wants to include unrestricted uses on a product with restricted uses then the entire product must be labeled restricted. This is to avoid the general public obtaining access to products with restricted uses. If the registrant desires to market uses as unrestricted, then the registrant should seek a separate registration only for those unrestricted uses. *40 CFR 156.10(j)*.

C. Wording of the RUP Terms of Restriction.

The label must bear the general summary statement of the terms of restriction at top of the front panel. *40 CFR 156.10(j)(2)(i)(B)*; see *Chapter 3* for correct formats.

1. If use is restricted to certified applicators, the general RUP statement listed at *40 CFR 156.10(j)(2)(i)(B)* must appear as follows: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification".

2. Some pesticides require a specific RUP statement, based on specific case-by-case risk management decisions. The Agency in some cases has determined that particular RUP statements are applicable to specific products or to the active ingredient(s). Check the appropriate science review, and consult your Product Manager or Team Leader to determine if a specific RUP statement has been applied to particular products or active ingredients. Then evaluate whether the particular product at issue requires that same or similar language based on risk management issues and the FIFRA statutory standard of unreasonable adverse effects. Also, check in OPPIN or the Chemical Review Manager/Team Leader for the status of the Reregistration Eligibility Decision (RED) document for the chemical. If a RED document has been issued, check it for any specific guidance for Restricted Use Pesticide classification and/or associated labeling. Following is an example of an RUP statement.

   "Restricted Use Pesticide (Same minimum type size as signal word)"

   "Due to (reason for restricted use)"

   For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

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Label Review Manual

Chapter 7: Precautionary Statements

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Table of Contents

What's changed in this version?

- Added *Table of Contents.*
- Added *What's changed in this version?* section.
- Updated hyperlinks.
- Reformatted text and style to improve readability.
- Added dermal sensitization to acute toxicity categories table (Table 1).
- Reinstated first aid statements per PR Notice 2001-1.
- Updated location of first aid statements per February 27, 2018 *First Aid Guidance Document – EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68.*
- Removed redundant section on NPIC and referenced Chapter 15 for details.
- Added Note to Physician statement for products containing zinc phosphide.
- Updated NPIC information in first aid statements example in Table 9.
- Changed *Labeling Options* section to *Modified precautionary statements for diluted products (aqueous solutions only).*
- Removed *Optional Labeling/Deviations* section and moved directions under its respective sections.

I. Introduction

The precautionary statements provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide, in addition to medical treatment instructions and information to reduce exposure potential. This chapter addresses the signal word, child hazard warning, hazards to humans and domestic animals statement, first aid statement, and personal protective equipment (PPE) information for product labels with uses not subject to the worker protection standard (WPS). Precautionary statements for WPS-PPE, user safety requirements, engineering controls, user safety recommendations, environmental hazards, and physical/chemical hazards are addressed in other chapters.

II. Documents used to determine precautionary statements

40 CFR 156.62 specifies the criteria for the acute toxicity categories for pesticide products, and 40 CFR 156.70 specifies the typical *Hazards to Humans and Domestic Animals* statement associated with each toxicity category. EPA has historically used the labeling statements in the September 26, 1984 proposed rule *Labeling Requirements for Pesticides and Devices* (49 FR 37960, Number 188) to supplement the precautionary statements in 40 CFR 156.62. 40 CFR 156.70(c) states that specific statements pertaining to the hazards of the product and its uses must be approved by the Agency.

During pesticide reregistration and re-evaluation, the reregistration eligibility decision (RED), interim decision, or final decision documents may also specify required label statements. In cases where these label requirements differ from those determined by the acute toxicity categories, the most protective statements must be employed. The regulations allow use of a signal word for human hazard for a higher product toxicity category when necessary to prevent unreasonable adverse effects on humans and the environment. 40 CFR 156.64(b)(1).

III. Acute toxicity classification

The signal word, hazards to humans and domestic animals, non-WPS PPE, and first aid statements are typically determined by the results of the six acute toxicity studies performed with the product formulation. The acute oral, acute dermal, and acute inhalation studies evaluate systemic toxicity via the designated routes of exposure. The primary eye irritation and primary skin irritation studies measure irritation or corrosion, while the dermal sensitization study evaluates the potential for allergic contact dermatitis. Except for dermal sensitization, each acute study is assigned to a toxicity category based on the study results (see Table 1 below). The results of these six acute toxicity studies must be known to determine the appropriate precautionary statements.

Table 1. Acute Toxicity Categories				
Study	**Category I**	**Category II**	**Category III**	**Category IV**
Acute Oral	LD_{50} ≤50 mg/kg	LD_{50} >50 – 500 mg/kg	LD_{50} >500 – 5,000 mg/kg	LD_{50} >5,000 mg/kg
Acute Dermal	LD_{50} ≤200 mg/kg	LD_{50} >200 – 2,000 mg/kg	LD_{50} >2,000 – 5,000 mg/kg	LD_{50} >5,000 mg/kg
Acute Inhalation	LC_{50} ≤0.05 mg/l	LC_{50} >0.05 – 0.5 mg/l	LC_{50} >0.5 – 2 mg/l	LC_{50} >2 mg/l
Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)
Dermal Sensitization	**Positive**		**Negative**	
	Product is a sensitizer or is positive for sensitization		Product is not a sensitizer or is negative for sensitization	

IV. Determining the precautionary labeling

A. Signal word

1. When required

A signal word is required for all registered pesticide products unless the pesticide product is classified as Toxicity Category IV for all routes of exposure, and is negative for dermal sensitization. If a signal word is used in this case, it must be "CAUTION." 40 CFR 156.64(a)(4).

2. Determining the signal word

The signal word is determined by the most severe toxicity category assigned to the five acute toxicity studies (see Table 1) 40 CFR 156.64. The signal words and its associated toxicity categories are as follows:

Toxicity Category I	**DANGER**
Toxicity Category II	**WARNING**
Toxicity Category III	**CAUTION**
Toxicity Category IV	None required (or **CAUTION** as optional)

Refer to the acute toxicity data review to determine the most severe toxicity category. Also check the Confidential Statement of Formula (CSF) to determine if methanol is present in concentrations of 4% or more. If so, the recommended signal word, regardless of the toxicity categories noted in the acute toxicity review, is "DANGER."

3. Location and prominence

The signal word must be placed on the front panel as a separate line in close proximity to the child hazard statement "Keep Out of Reach of Children." 40 CFR 156.60. It must also be placed with the heading for the human precautionary statement section of the labeling. 40 CFR 156.64. Also, the signal word must be on any supplemental labeling intended to accompany the product in distribution or sale. 40 CFR 156.60.

The Agency prefers that the signal word be placed directly below the child hazard statement. The signal word should appear in the Precautionary Statements section immediately below the subheading "Hazards to Humans and Domestic Animals." In cases where the first aid and "Hazards to Humans and Domestic Animals" statements appear on the front panel, the signal word should be placed directly below the "Keep Out of Reach of Children" statement, but it does not have to be repeated after the "Hazards to Humans and Domestic Animals" statement.

All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to assure that they will not be overlooked under customary conditions of purchase and use. 40 CFR 156.60(b). The signal word must appear in all capital letters and should be oriented in the same direction as other label text. See Chapter 3 of this Manual for font size requirements.

4. Related information on California Proposition 65 warnings

Because of the potential for confusion, the Agency historically has not approved labels containing the terms "caution," "warning," or "danger," unless it is the signal word for that label (e.g., "CAUTION: Wash hands before eating or smoking" on a label with the signal word of "CAUTION"). If the Prop 65 term would conflict with the EPA signal word, then registrants should use "Notice" or "Attention" for the Prop 65 statement so that it does not conflict with the EPA signal word.

B. Poison – skull and crossbones symbol

1. When required

The word "POISON" and the skull and crossbones symbol ☠ are required for products classified as toxicity category I for acute oral, acute dermal, or acute inhalation toxicity studies. 40 CFR 156.64(a)(1). Additionally, if a formulation contains ≥4% methanol, the addition of "POISON" and the skull and crossbones symbol are recommended because of the well-known possible risk of causing blindness.

Table 2. Examples of Signal Word Determination

Study/Classification	Product A	Product B	Product C	Product D	Product E
Acute Oral	III	IV	I	III	III
Acute Dermal	IV	III	III	IV	III
Acute Inhalation	III	IV	III	III	III
Primary Eye	III	II	I	I	III
Primary Skin	IV	IV	II	IV	III
Special Inert (e.g., methanol)	No	No	No	No	Yes
CORRECT SIGNAL WORD	**CAUTION**	**WARNING**	**DANGER POISON ☠**	**DANGER**	**DANGER POISON ☠**

2. Location and prominence

If required, the word "POISON" and the ☠ symbol must appear in immediate proximity to each other. The word "POISON" must appear in red on a background of a distinctly contrasting color. It should appear near the signal word "DANGER." 40 CFR 156.64(a)(1).

C. Child hazard warning statement

1. When required

The child hazard warning statement "Keep Out of Reach of Children" is required on all product labels regardless of toxicity category, unless EPA waives the requirement or requires or permits an alternative child hazard warning. The child hazard warning statement requirement may be waived or modified when the registrant adequately demonstrates that the likelihood of contact with children during distribution, storage, or use (e.g., an MUP in some situations) is remote or if the pesticide is approved for use on infants or children. 40 CFR 156.66.

2. Location and prominence

The child hazard warning statement must appear on the front panel and on a separate line in close proximity to the signal word. 40 CFR 156.66(a). The Agency prefers the child hazard warning statement to be located above the signal word. The child hazard warning statement should also be oriented in the same direction as other label text.

3. Additional information

Based on the FIFRA unreasonable adverse effects standard, the Agency has not allowed the Precautionary Statements or the Directions for Use to contain any statement which implies that the product may be used by children. For example, draft labels of products intended to repel insects should not contain instructions such as *"Do not allow use by small children without close adult supervision."* Such labeling creates unacceptable risk issues, as it implies that a child can apply the product if an adult is present.

A modified child hazard warning statement may be used for products where child contact is expected during normal use. For products required or permitted to use a modified statement, the statement should be appropriate for the use pattern (e.g., *"Do not allow children to apply product," "Do not allow children to play with pet collar."*)

D. Hazards to Humans and Domestic Animals Statements

1. When required

Hazards to Humans and Domestic Animals statements are required for products classified as toxicity categories I, II, or III, or positive for skin sensitization. Hazards to Humans and Domestic Animals statements may specify both mandatory actions and advisory information.

2. Required header

The Hazards to Humans and Domestic Animals statements must appear under the section heading "Precautionary Statements" and below the subheading "Hazard to Humans and Domestic Animals." Additionally, the signal word must immediately precede the precautionary paragraph. 40 CFR 156.70. The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product. 40 CFR 156.70(a).

3. Location and prominence

The Hazards to Humans and Domestic Animals section may appear on any panel. The Agency strongly prefers that the statements be organized so that the most severe routes of exposure (by toxicity classification) are listed first.

4. Determining the Hazards to Humans and Domestic Animals statements for fumigant products

Refer to PR Notice 84-5, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

5. Determining the Hazards to Humans and Domestic Animals statements for non-fumigant products

Statements from Tables 3-8 below may be selected based on the toxicity category assigned to each route of exposure. Statements from these tables should be combined to form a concise paragraph. Repetitious sentences should be omitted. In cases where the toxicity categories are unknown and a regulatory decision was made, the precautionary labeling must be consistent with the signal word. Refer to Section IV.E. and Chapter 10 of this Manual for selecting the appropriate protective equipment to include for non-WPS products.

6. Applicability

Hazards to Humans and Domestic Animals statements must be appropriate for all uses on the label. These statements must be consistent with each use pattern listed on the label. The statement should not include precautionary measures that are reasonably beyond the control of the typical applicator. Hazards to Humans and Domestic Animals statements must not require use of specialized equipment which would not be readily available to the typical user of the product (e.g., specialized respirator equipment for a consumer product).

7. Alternative Hazards to Humans and Domestic Animals statements

Registrants may submit Hazards to Humans and Domestic Animals statements which reflect specific hazards. 40 CFR 156.70(c). Such requests must be supported by data (or substantive justification) and approved by EPA (e.g., *"Do not remove contact lenses, if worn. Get immediate medical attention."*).

8. Products containing methanol

If a product contains ≥4% methanol, the following statement should be included to mitigate potential risk:

"Methanol may cause blindness."

Table 3. Typical Statements for Acute Oral Toxicity		
Category	**Signal Word**	**Statement**
I	DANGER POISON ☠	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
IV	CAUTION (optional)	*No statement is required. May use Category III statement.*

Table 4. Typical Statements for Acute Dermal Toxicity		
Category	**Signal Word**	**Statement**
I	DANGER POISON ☠	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (*specify appropriate protective clothing*). Remove and wash contaminated clothing before reuse.
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (*specify appropriate protective clothing*). Remove and wash contaminated clothing before reuse.
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear (*specify appropriate protective clothing, if applicable*).
IV	CAUTION (optional)	*No statement is required. May use Category III statement.*

Table 5. Typical Statements for Acute Inhalation Toxicity		
Category	**Signal Word**	**Statement**
I	DANGER POISON ☠	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist)[1]. Wear (*specify appropriate respiratory protection*). Remove and wash contaminated clothing before reuse.
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist)[1]. Wear (*specify appropriate respiratory protection*). Remove and wash contaminated clothing before reuse.
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor, or spray mist)[1]. Remove and wash contaminated clothing before reuse.
IV	CAUTION (optional)	*No statement is required. May use Category III statement.*

[1] Choose the word which appropriately describes the product formulation type during use.

Table 6. Typical Statements for Primary Eye Irritation

Category	Signal Word	Statement
I	DANGER	Corrosive[1]. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear (*specify appropriate protective eyewear*). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear (*specify appropriate protective eyewear*). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.
III	CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear (*specify appropriate protective eyewear, if applicable*). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
IV	CAUTION (optional)	*No statement is required. May use Category III statement.*

[1] Required only if corrosive effects were observed during the study.

Table 7. Typical Statements for Primary Skin Irritation

Category	Signal Word	Statement
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes, on skin, or on clothing. Wear (*specify appropriate protective clothing and gloves*). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wear (*specify appropriate protective clothing and gloves*). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear (*specify protective clothing and gloves, if applicable*).
IV	CAUTION (optional)	*No statement is required. May use Category III statement.*

Table 8. Typical Statements for Dermal Sensitization

Study Result	Statement
Positive	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals[1].
Negative	*No statement is required.*

[1] A positive dermal sensitization study for a Category IV product does not trigger PPE requirement.

E. Personal Protective Equipment (PPE)

PPE requirements are specified for uses covered under the WPS, but there are no regulatory requirements for non-WPS products, products used by residents, or products intended only for manufacturing use. However, to protect human health, the following guidance is offered.

1. For non-WPS uses (industrial/commercial)

Label reviewers should ensure that adequate, understandable language regarding the types of PPE that should be worn for the product's hazards is included in any label, whether it is RUP or not. In cases where the reviewers determine PPE would be necessary, the various PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. If there is an applicable regulatory document which specifies PPE requirements based on concerns specific to the active ingredient, then those PPE requirements must be placed on the label.

2. For products used by residents/consumers

To protect human health, label reviewers should review the toxicity data and the product's uses to determine whether PPE would be necessary to meet the standards for registration. In cases where the reviewer determines PPE would be necessary, the PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. In some cases, the PPE indicated in these tables may need to be modified; for example, to fit the consumer's ability to acquire it. For instance, "shoes" may need to be substituted for "chemical-resistant footwear," or "safety glasses" may need to be substituted for "protective eyewear." If there is an applicable regulatory document which specifies PPE requirements based on concerns specific to the active ingredient, then those PPE requirements must be placed on the label.

F. First Aid statement

1. When required

A first aid statement is required when any acute toxicity study result is classified as category I, II, or III. 40 CFR 156.68. Including the first aid statements for products classified as category IV is acceptable, but not required.

2. Appropriate headers

The first aid statements should appear under either the heading "First Aid" or "Statements of Practical Treatment." 40 CFR 156.68(c) and PR Notice 2001-1. The heading "First Aid" is preferred by the Agency. In addition, EPA historically has not allowed the heading "Antidote" in conjunction with the first aid

statements unless a specific antidote is necessary.

3. Location and prominence

First aid statements shall appear on the front panel of the label for all products classified as toxicity category I (40 CFR 156.68). The Agency may, however, permit reasonable variations in the placement of the first aid statement as long as the reference statement "See First Aid (or Statement of Practical Treatment) on (*identify appropriate panel*)." appears on the front panel, preferably near "Poison" and the skull and crossbones symbol.

First aid statements for toxicity category II and III products may appear on any panel of the label. The Agency does *not* require the first aid statements for toxicity category II and III products to bear the first aid statements on a *visible* panel. For additional information on the Agency's position regarding the location of the first aid statement, see EPA's February 27, 2018 guidance document *First Aid Guidance Document – EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68* located under docket ID EPA-HQ-OPP-2016-0545. However, any time first aid statements appear other than on the front panel, then a referral statement such as "See side/back panel for First Aid." should appear on the front panel in close proximity to the signal word. Furthermore, first aid statements on the side or back panel should be grouped near other precautionary labeling text, yet set apart or distinguishable from the other label text. The Agency strongly prefers that the statements be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.

4. Determining the first aid statements for fumigant products

Refer to PR Notice 84-5, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

5. Determining the first aid statements for non-fumigant products

Review Table 9 to determine the preferred first aid statements for each route of exposure. Registrants should support alternative first aid statements with medical evaluations of the product. Approval of alternative first aid statements is guided by considerations such as those set out in the "Content and Clarity" section below. The Agency has not approved the use of salt water for emesis as a first aid technique. PR Notice 80-2.

a) Content and clarity

First aid statements should be written in brief, clear, simple, and straightforward language so that the average person in an emergency

can easily and quickly understand the instructions. First aid statements should apply to all ages or when necessary, include distinctions between the treatments for different ages (e.g., children vs. adults). Any reasonably competent individual should be able to carry out the instructions in the first aid statements. These statements should not include procedures which must be performed by medical personnel or require specialized equipment. Such procedures belong under the Note to Physician heading (see Section IV.G. below).

b) Acute dermal and primary skin irritation

Because both of these studies focus on the dermal route of exposure, any first aid statements required by the results of these two studies can be combined. Use the first aid statement required for the acute dermal toxicity study if the results of both studies place the product in the same acute toxicity category. Use the statements for the more severe acute toxicity category if the results of the studies would place the product in different acute toxicity categories.

c) Eye and skin irritation

If the product is corrosive and is in toxicity category I or II for eye or skin irritation, then a first aid statement for ingestion may also be included. First aid statements for ingestion may be more appropriate for products with some potential for ingestion, such as liquid concentrates, but less so for products with low potential, such as aerosol sprays. For Toxicity Category I skin and eye irritants, the Agency has used the statement (PRN 2001-1):

> *"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."*

6. Products that contain an organophosphate or an N-methyl-carbamate

If the product contains either an organophosphate (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase) the following phrase should be included in the first aid statement (PRN 2001-1):

> *"Contains a/an _____ (*either organophosphate or N-methyl-carbamate*) that inhibits cholinesterase."*

7. Products that contain zinc phosphide

If the product contains zinc phosphide, the following first aid statement for ingestion is recommended (PRN 2001-1):

> *"If swallowed: Immediately call a poison control center or doctor or transport the person to the nearest hospital. DO NOT DRINK WATER. Do not administer anything by mouth or make the person vomit unless advised to do so by a doctor."*

8. Products that contain petroleum distillates

If the product contains ≥10% petroleum distillate, the following first aid statement for ingestion should be used (PRN 2001-1):

> *"If swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person."*

However, if registrants have data to show there is benefit in drinking water or milk after ingesting the product, they may use alternate wording.

9. Telephone numbers

EPA encourages, but does not require, registrants to include a company telephone number or toll-free hotline number for emergency information in the first aid section. If a number is included, confusion can be avoided by specifying emergency vs. non-emergency numbers. If a phone number is included, it should include a phrase or statement indicating the kinds of information the number should be used for and it may include hours of service. For example:

> *"Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information on this product, call (1-XXX-XXX-XXXX), Monday through Friday, 9 a.m. to 5 p.m. For medical emergencies, call the poison control center at 1-800-222-1222."*

If a registrant does not have its own non-emergency number, the registrant may reference the National Pesticides Information Center (NPIC) (see Chapter 15). Note that the NPIC does not provide emergency medical information.

Table 9. First Aid Statements		
Route of Exposure	**Category**	**Statement**[1]
Ingestion treatment for acute oral toxicity	I, II, III	If swallowed: - Call a poison control center or doctor immediately for treatment advice. - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to do so by a poison control center or doctor. - Do not give anything by mouth to an unconscious person.
	IV	No statement is required. May use statement above.
Skin exposure treatment for acute dermal toxicity and primary skin irritation	I, II, III	If on skin or clothing: - Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
	IV	No statement is required. May use statement above.
Inhalation treatment for acute inhalation toxicity	I, II, III	If inhaled: - Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. - Call a poison control center or doctor for treatment advice.
	IV	No statement is required. May use statement above.
Eye exposure treatment for primary eye irritation	I, II, III	If in eyes: - Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for treatment advice.
	IV	No statement is required. May use statement above.
General information to include near the first aid statement		
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. - For medical emergencies, call the poison control center at 1-800-222-1222. - For general information on this product, call 1-XXX-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu.		

[1] Use alternate statements if these are medically inappropriate for the product (e.g. if the product contains zinc phosphide or ≥10% petroleum distillate).

G. Note to Physician

1. When used

For fumigant products, refer to PR Notice 84-5, Registration Standards, REDs, or other regulatory decision documents for appropriate statements.

For non-fumigant products, the following criteria are used to determine whether a Note to Physician is needed:

(a) All products that are classified as Toxicity Category I.

(b) Products which are corrosive or classified as Toxicity Category I for eye or skin. These products must include the following Note to Physician:

"Probable mucosal damage may contraindicate the use of gastric lavage."

(c) Products which contain ≥10% petroleum distillate. These products should include the following Note to Physician:

"Contains petroleum distillate. Vomiting may cause aspiration pneumonia."

(d) Products which contain zinc phosphide. The products should include the following Note to Physician:

"Contains the phosphine-producing active ingredient zinc phosphide. Probable mucosal damage may contraindicate the use of gastric lavage."

(e) Products which produce physiological effects requiring specific antidotal or medical treatment such as: cholinesterase inhibitors (e.g., carbamates, phosphorothioates, and organophosphates); metabolic stimulants (e.g., dichlorphenols); or anticoagulants (e.g., warfarin).

2. Location and prominence

The Note to Physician should be located in close proximity to the first aid statements, but should be clearly distinguished from it. It should not be placed within the first aid statements, but should appear below the last first aid statement.

3. Contents of Note to Physician

The Agency does not provide specific statements except for the cases described above. However, the Note to Physician should include or address the following information, as appropriate:

- Technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide; and
- a company telephone number to specific medical personnel who can provide specialized medical advice.

V. Modified precautionary statements for diluted products (aqueous solutions only)

A. When used

Modified Hazards to Humans and Domestic Animals and first aid statements which correspond with the toxicity categories associated with a product's use when diluted with water may be allowed on product labels provided the following data and label requirements are met. All data and modified precautionary statements for use dilutions must be reviewed and approved by the Agency. 40 CFR 156.70(c).

B. Data requirements

In some cases, use dilution labeling statements triggered by systemic toxicity (i.e., acute oral, dermal, or inhalation toxicity) may be supported by extrapolation from the LD_{50}/LC_{50} for the concentrate. At a minimum, the following information must be submitted for Agency consideration:

(a) A slope calculated from at least three, and preferably more, dose levels having partial responses (i.e., a well characterized dose-response);

(b) Dose groups sufficiently large (>5 per group) to allow for the calculation of confidence limits that fall within the defined toxicity category boundaries;

(c) Extrapolation to higher toxicity categories will only be applied to water dilutions. It should also be determined that there are no other factors affecting the toxicity of the end-use product (e.g., inert ingredients that enhance the absorption of the active ingredient, promote the active ingredient's toxicity, etc.). Other types of extrapolations will be done on a case-by-case basis.

(d) Use dilution Hazards to Humans and Domestic Animals statements triggered by skin or eye irritation must be supported by new or cited studies. If another registered diluted product (such as a ready-to-use formulation) has acceptable data and is found similar to the concentrated product after it has been diluted, those data may also be used to support modified labeling.

C. Labeling requirements

It is not the Agency's intent to allow two sets of Hazards to Humans and Domestic Animals statements and/or first aid statements on the label. Rather, EPA will allow certain modified statements to be added that are applicable for use dilutions. These additional statements, triggered by the toxicity category of the most concentrated use

dilution, must be placed directly after the required statements for the concentrate, and may not substitute the required statements for the concentrate. If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. 40 CFR 156.68(b) and 40 CFR 156.70(c).

If a product label does include modified use dilution statements, the signal word must still reflect the toxicity of the [concentrated] product as distributed or sold. 40 CFR 156.64(b)(2). The following examples show where modified statements (in italics) should appear on product labeling:

> Hazards to Humans and Domestic Animals:
>
> "Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. *After product is diluted in accordance with the directions for use, goggles or face shield are not required."*
>
> First Aid:
>
> "If on skin or clothing: Wash with plenty of soap and water. Get medical attention. *If product, diluted in accordance with the directions for use, gets on skin, medical attention is not required."*

- If a registrant with an identical or substantially similar product is relying/citing a product that has modified use dilution precautionary statements, those modified use dilution statements are not required to be on their product. Only the precautionary statements for the concentrated product (as distributed or sold) is required.

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Label Review Manual

Chapter 8: Environmental Hazards

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I. Introduction

The Environmental Hazards statement provides the precautionary language informing users of the potential hazards to the environment from transport, use, storage, or spill of the product. These hazards may be to water, soil, air, beneficial insects, plants, and/or wildlife as identified in risk assessments performed by the Environmental Fate and Effects Division. Generally, the information contained in this section is based upon the results of eight basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These eight studies are: (1) avian oral LD_{50} (with mallard *or* bobwhite quail), (2) avian dietary LC_{50} (mallards), (3) avian dietary LC_{50} (bobwhite quail), (4) freshwater fish LC_{50} (rainbow trout), (5) freshwater fish LC_{50} (bluegill sunfish), (6) acute LC_{50} freshwater invertebrates *(Daphnia magna* or water flea), (7) honeybee contact LD_{50}, and (8) mammalian acute oral LD_{50}. For specific data requirements: *40 CFR Part 158*.

In addition, data concerning a product's potential to be transported to groundwater, surface water, aquatic sediment, to drift, to adversely affect non-target plants and bees provide important information. Data include, but are not limited to, results from hydrolysis, batch equilibrium, aerobic soil metabolism, field dissipation, and prospective groundwater studies.

The data generated from all of these studies support the language used for the Environmental Hazards statements. Review of the data is performed by the Environmental Fate and Effects Division (EFED) or other science reviewers who may also evaluate any label text proposed by the registrant to determine what statements are required.

The label reviewer should consult with the product manager/team leader and EFED or science reviewer for chemical specific statements, such as groundwater/surface water, spray drift/runoff, or endangered species statements that will be added to the label as they are identified.

II. Reviewing the statements

A. When Required

The label reviewer must first determine whether the use patterns on the label require any Environmental Hazards statement. The use pattern of a pesticide helps determine the need for and the specific text of the Environmental Hazards section. The label reviewer may assume that any pesticide product used outdoors must include the Environmental Hazards statement on the label. However, the reviewer should also look at the proposed statement with a critical eye towards its applicability. Does it make sense for the product? For example, a granular herbicide would not generally need a statement warning of potential spray drift problems since granular formulations are not "sprayed" and are seldom associated with any "drift".

1. **Exclusively Indoor Products.** Products which are intended for use exclusively *indoors* may omit the Environmental Hazards statement. Products applied to domestic animals, such as flea collars or ear tags may in most cases omit the statement. However, the statement may be required for a domestic-use product such as a dog dip due to the potential for contamination of water by the use of such a product. Thus it is important for reviewers to carefully evaluate the use pattern of the product to determine whether potential risk from the transport, use, storage or disposal of the product should be mitigated by the Environmental Hazards statement.

2. **Manufacturing Use Products (MPs).** Although used indoors to formulate other products, MPs may require some Environmental Hazard statements text because MPs may be highly concentrated and could pose a serious hazard if a spill occurred. A discharge statement may also be required; see section VII. A. below for recommended language.

3. **Outdoor Use Products.** The Agency has typically required products labeled for use outdoors to have Environmental Hazards statements on their labels. 40 CFR 156.80 – 156.85. If the reviewer determines that the use pattern triggers the need for Environmental Hazards labeling, the proposed draft labeling must be reviewed according to the requirements outlined in the regulations.

B. Statement Location

The Environmental Hazards section of the label should be located under the general heading "Precautionary Statements". It *must* have the heading "Environmental Hazards" (not "Environmental Precautions", "Environmental Protections", or anything similar). (*40 CFR Part 156.80(b)*).

C. Support for Statements

The text of the proposed Environmental Hazards statements is then reviewed according to the type of product. If the action represents a submission accompanied by data, the environmental science reviewer will evaluate the environmental hazards statements and recommend any necessary label changes as part of the data review. The label reviewer must specify all requested changes in the response to the registrant, and assure that the changes are in accordance with mandatory/advisory guidance. (*Chapter 3* and *PR Notice 2000-5*)

1. **Technical/End-Use Products.** The environmental reviewer is responsible for reviewing data on all technical products and may also review data associated with end-use formulations. Data requirements are governed by FIFRA and the implementing regulation set out in *40 CFR Part 158*. Generally, data are required when an end-use formulation is likely harmful to non-target organisms (for example, micro-encapsulated insecticides which are used on crops are potentially harmful to pollinators). If a Reregistration Eligibility Decision (RED) Document has been issued, it may contain appropriate Environmental Hazards statements, but the reviewer should evaluate

whether the decision document specifically addresses the use at issue and then make appropriate changes to the label statement.

2. **Identical or Substantially Similar Products.** If the label reviewer is working on an application for registration for an identical or substantially similar product, the Environmental Hazards statements of the similar formulation should be compared with those in the RED. If the similar registered product label language is consistent with the RED, the identical or substantially similar product Environment Hazard language should be the same as the currently registered product. If there are no similar products, route the application to EFED or the science reviewers. Additionally, if a registrant wishes to amend the Environmental Hazards statements, environmental reviewers may need to see the amendment application.

   Since the cited label may have some statements that are outdated and/or missing (required or recommended since the label was accepted), it is important to check the regulations and the statements outlined in the rest of this chapter to make sure that both the cited label and the draft label reflect current Agency requirements and policy.

   If an error is discovered in the Environmental Hazards section of the cited identical or substantially similar product label, the reviewer should send a letter informing the registrant of the cited identical or substantially similar product label of the error(s) and request an application for amendment be submitted within a reasonable time, such as 30 days.

III. General statements

A. Outdoor, Terrestrial Uses

Generally, all products with directions for outdoor, *terrestrial* uses should have the following statements in the Environmental Hazards section:

> *"For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate".*

These statements are preceded by "**For terrestrial uses**", to make it clear that the statements **do not** apply to the other general use patterns—e.g., aquatic uses such as mosquito larvicides, aquatic herbicides, piscicides, etc.,or greenhouse and indoor uses.

Aerial Forestry Application Statement. If a pesticide product is aerially applied to forests, the above statements should be preceded with the phrase:

> "For terrestrial uses, except when applying aerially over the forest canopy:"

There are many creeks and streams under forest canopies. The statement as written allows spraying the forest canopy, but requires spray valves to be shut off when passing over ponds, streams, etc. that are not under the forest canopy.

B. *Bacillus thuringiensis* (Bt)

For Bt products that are intended for forestry treatments or aquatic uses (e.g. mosquito control with *Bt israelensis*), variations of the above Environmental Hazards statements may be required.

1. **Forestry Uses.** For forestry uses, the statement should read:

   "Do not contaminate water when disposing of equipment washwaters or rinsate".

2. **Aquatic Uses.** For aquatic uses, the statement should read:

   "Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption".

C. Outdoor, Residential Consumer Products

For outdoor residential consumer products (except for lawn care products applied by a Pest Control Operator which use the same statement as outdoor terrestrial uses), the statements preferred by the Agency to meet risk/benefit concerns are as follows (See *PR-Notice 2008-1*).

Table 1. Outdoor Residential Consumer Product Statements

Formulation type	Preferred Language
Liquid Concentrate	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.
Broadcast Granular	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.
Dust	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

Formulation type	Preferred Language
Liquid Ready-to-Use (RTU)	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

These statements provide the basic use instructions for avoiding water and other environmental contamination; they are used in addition to other required environmental statements, such as wildlife hazard statements determined by the toxicology data (e.g., specific precautionary statements concerning bees, fish or aquatic organisms).

The reviewer must also keep in mind the use pattern of the product undergoing a label review. If the product is actually intended for application to water to control algal growth, for example the above statements may be inappropriate as written.

D. Outdoor, Terrestrial Products Requiring Fish or Aquatic Invertebrate Statements

Products with directions for outdoor terrestrial uses requiring a fish or aquatic invertebrate toxicity statement usually contain a statement warning of hazard from drift and/or runoff. The word *drift* should be omitted if the product is a "granular" or if it is applied "in furrows" or injected into the soil. The Agency has historically required that the following statement appear in the Environmental Hazards section:

> *"Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas".*

E. Groundwater Label Advisories

There are two groundwater label advisory options available. The need for a groundwater label advisory is based on the environmental fate properties of the chemical and/or detections of the chemical in groundwater. One option is for chemicals with little or no monitoring data that have environmental fate properties similar to pesticides that have been found in groundwater. The other option is for chemicals that have actually been found in groundwater.

1. **Based on Laboratory/Field Data.** If no detections are reported in groundwater (for example, a new chemical) but the chemical (or a major degradate) has a combination of environmental fate properties similar to other pesticides found in groundwater as a result of normal label uses:
   - mobility characteristics (e.g. K_d less than 5, or field dissipation results that indicate the chemical leaches)
   - persistence characteristics (e.g., hydrolysis half-life greater than 30 days at any pH or aerobic soil metabolism half-life greater than 2 weeks)

then the Agency has generally required the following label language:

*"**Groundwater Advisory***

This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow".

2. **Based on Groundwater Monitoring.** If detections are reported in groundwater in a prospective groundwater study or other monitoring study conducted for registration, or other reliable monitoring data in the publicly available literature, then the Agency has generally required the following label language:

*"**Groundwater Advisory***

[Name of chemical] [A degradate of (name of chemical)] is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow",

F. Surface Water Label Advisories

When appropriate, after the environmental assessment, the Agency requires the following statement to be added to outdoor household/residential, agricultural, and other outdoor labels modified for the specific pesticide characteristics and targeted audience.

"This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water.

This product is classified as having [insert phrase 1.a., 1.b., or 1.c., according to the pesticide's "mean" soil partition coefficient (K_d)] for [insert phrase 2.a., 2.b., or 2.c. according to the pesticide's aerobic soil metabolism half-life]. [insert phrase 3.a or 3.b depending on whether the product is intended for the household user or farmer]",

1. **Soil Partition Coefficient Phrases**

   (a) K_d less than 15 – "*high potential for reaching surface water via runoff*"

   (b) K_d between 15-300 – "*a medium potential for reaching both surface water and aquatic sediment via runoff*"

   (c) K_d greater than 300 – "*high potential for reaching aquatic sediment via runoff*"

2. **Aerobic Soil Metabolism Half-Life Phrases**

   (a) $t_{1/2}$ less than 8 days – *"several days after application"*

   (b) $t_{1/2}$ between 8 and 30 days – *"several weeks after application"*

   (c) $t_{1/2}$ greater than 30 days – *"several months or more after application"*

3. **Targeted User Community**

   (a) Household/Residential Label

   See Table 1 on page 8-4.

   (b) Agricultural Label

   "A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of [Name of chemical] [A degradate of (name of chemical)] from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.. [For pesticides with a soil partition coefficient greater than 300 add the following, *"Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff".*]

IV. Non-target organism statements

A general requirement for products to bear environmental hazard statements, including hazards to non-target organisms, is stated at 40 CFR Part 156.80. In Part 156.85, examples are given of statements the Agency typically requires when data indicate certain acute toxicity levels for mammals, birds, fish, etc., or there is other information such as accident history indicating significant risks to non-target wildlife. Other statements than those listed may be required if more appropriate to the formulation or use.

A. Hazard Statements for Birds, Mammals, Fish, Aquatic Invertebrates and Estuarine Organisms

This information will be found in submitted data, the RED document, or the Registration Standard. It may not necessarily be available to the label reviewer, but helps you to understand the origin of the statements

1. **Bird and Mammal Hazard Statement.** The following statement has typically been required when a pesticide intended for outdoor use contains an active ingredient which has a mammalian acute oral $LD_{50} \leq 100$ mg/kg, an avian acute oral $LD_{50} \leq 100$ mg/kg, or a subacute dietary $LC_{50} \leq 500$ ppm:

"This pesticide is toxic to [birds] [mammals] or [birds and mammals]".

2. **Fish/Aquatic Invertebrate Statement.** The following statement has typically been required when a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} or aquatic invertebrate (including estuarine species such as oyster and mysid shrimp) $EC_{50} \leq 1$ ppm:

   "This pesticide is toxic to [fish] [fish and aquatic invertebrates] [oysters/shrimp] or [fish, aquatic invertebrates, oysters and shrimp]".

3. **Incident Data Statement.** If field studies or accident history, such as the FIFRA 6(a)(2) reports, indicate that use of the pesticide may result in fatality to birds, fish or mammals, the following statement has typically been required:

   "This pesticide is extremely toxic to [birds], [mammals], [fish], or [birds and mammals and fish]".

B. Pollinating Insect Hazard Statements

If a pesticide is used outdoors as a foliar application, and is toxic to pollinating insects, a "Bee Hazard" warning has generally been required to be included in the Environmental Hazards. See *40 CFR § 156.85(a)*. The following table sets out the toxicity groupings and examples of label statements for honey bees and other pollinating insects. Crop-specific use instructions would optimize bee and other pollinating insect safety. There may be other options for mitigating risk that may be considered (i.e. applications at night for continuously blooming crops).These instructions could be placed in the Directions for Use.

Table 2. Pollinating Insect Acute Toxicity Groups and Precautionary Statement Examples

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
I Product contains any active ingredient with acute LD_{50} of 2 micrograms/bee or less	*This product is highly toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees or other pollinating insects are visiting the treatment area.*	*This product is highly toxic to bees and other pollinating insects exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees or other pollinating insects are actively visiting the treatment area.*

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
II Product contains any active ingredient(s) with acute LD_{50} of greater than 2 micrograms/bee but less than 11 micrograms/bee.	*This product is moderately toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees or other pollinating insects are visiting the treatment area.*	*This product is toxic to bees and other pollinating insects exposed to direct treatment. Do not apply this product while bees or other pollinating insects are actively visiting the treatment area.*
III All others.	No bee or pollinating insect caution required.	No bee or pollinating insect caution required.

Potential chronic hazards to honey bees, and other pollinating insects, and the resulting label language will be dealt with on a case-by-case basis. The Agency is in the process of developing chronic toxicity label statements for pollinator protection. When the proposed language has been thoroughly vetted, the appropriate conditions and statement will be included.

C. Aquatic Weed Control Label Statement

If a pesticide product is used to control aquatic weeds, the Environmental Hazards section generally is required to contain the following statement:

> *"Treatment of aquatic weeds can result in oxygen loss from decomposition of dead weeds. This loss can cause fish suffocation. Therefore, to minimize this hazard, treat ⅓ to ½ of the water area in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outwards in bands to allow fish to move into untreated areas. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed".*

D. Irrigation Water Label Statement

If a pesticide product is applied to irrigation water and contains an ingredient requiring an aquatic organism toxicity statement, the Environmental Hazards section generally must contain the following statement:

> *"Irrigation water treated with this product may be hazardous to aquatic organisms. Treated water must either be held on the irrigated field until sorbed by the soil or not released for (number) days after application".*

V. Mosquito control label statements

Pesticide products that include directions for mosquito control may require one of the following statements in the Environmental Hazards section, although the aquatic toxicity of the specific product may lead to more or less stringent statements. For example, certain bacterial larvicides, such as some Bt products, are considered non-toxic to aquatic organisms and would not require any statement. Some pyrethroids registered as mosquito adulticides are highly toxic to aquatic organisms and may require stronger precautions than those listed below, tailored to the specific products, in order to prevent adverse effects to water quality. Products with aquatic toxicity concerns between these extremes should have the following recommended statement, as appropriate:

A. Larvicides

"Aquatic organisms may be killed in waters where this pesticide is used. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed".

B. Adulticides

PR Notice 2005-1 lays out seven specific adult mosquito control label recommendations and details Agency rationale for these statements. Pesticide manufacturers are being requested to incorporate these statements in the labeling of any new products seeking registration for adult mosquito control use, or to request amendments of existing labels with this use pattern.

These recommendations apply only to products labeled for wide-area application as Ultra Low Volume (ULV) sprays or fogs, and not to home and garden use products which list mosquitoes on the label, or to coarse non-ULV sprays intended for residual treatment of vegetation or other surfaces. Control of mosquito larvae in water is a completely different use pattern from adult mosquito control, and is not included in the scope of *PR Notice 2005-1*.

1. Adult mosquito control applications should be limited to trained personnel. It is the Agency's position that the following statement should appear on the label of non-restricted use products for wide-area adult mosquito control:

   "For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision".

2. Products labeled for wide-area adult mosquito control should not bear container labeling for uses unrelated to adult mosquito control. The standard terrestrial use water hazard statement should not appear on product containers labeled solely for mosquito control. If a container label includes non-mosquito control use directions, those directions and

associated precautions should be clearly distinguished from those applicable to mosquito control. The terrestrial use statements on a mixed-use label should be followed by the statement:

"See separate directions and precautions for mosquito control applications".

3. Label statements intended to protect bodies of water and aquatic life should be harmonized, as well as improved to assist effective mosquito control applications. The Agency recommends the following statement to appear on mosquito adulticide labels:

   "This pesticide is [toxic/extremely toxic] to aquatic organisms, including [insert general types of organisms]. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to [insert general types of organisms]. [If appropriate, insert any additional wildlife hazard statements]. [Bee precaution can be inserted here or as a third paragraph of this section of the label]. [Insert consultation with state/tribal agency statement].

   Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters".

4. Users should consult with the State or Tribal agency for pesticide regulation to determine if permits or other regulatory requirements exist. The Agency concludes that the following statement is appropriate for all wide-area mosquito control product labels:

   "Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist".

5. Labels should specify a spectrum of spray/fog droplet sizes, and indicate that droplet size should be determined according to directions from equipment manufacturers or other appropriate sources. The following language is recommended as a model for droplet size calibration instructions on adulticide labels:

   "Ground-based application:

   Spray equipment must be adjusted so that the volume median diameter is less than [X = value to be provided by registrant] microns (Dv 0.5 < X μm) and that 90% of the spray is contained in droplets smaller than [Y = value to be provided by registrant] microns (Dv 0.9 < Y μm). Directions from the

equipment manufacturer or vendor, pesticide registrant or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated".

"Aerial Application:

Spray equipment must be adjusted so that the volume median diameter produced is less than (A = value to be provided by registrant] microns (Dv 0.5 < A μm) and that 90% of the spray is contained in droplets smaller than [B = value to be provided by registrant] microns (Dv 0.9 < B μm). The effects of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated".

6. Precautionary language to protect bees should have a provision to allow mosquito control applications in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or disease cases in animals or humans. The following language should be added to the last sentence of the bee precaution statement on the labels of mosquito adulticide products:

   "... (do not apply to blooming crops or weeds when bees are visiting the treatment area), except when applications are made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease-causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort".

7. Mosquito adulticide labels should include limits on timing and number of applications to the same location. Exceptions to these limits may be allowed in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or diseases cases in animals or humans. The following language should be included in the directions for use section of the label:

   "Do not re-treat a site more than once in [X hours/days]; no more than [Y] applications should be made to a site in any [Z weeks/months] or [one year]. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or

vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort".

In addition to the label language recommended in *PR Notice 2005-1*, the following information is recommended to add to the labels for adult mosquito control products, based on label requirements issued in REDs for these products:

- Maximum amount of active ingredient per acre/year
- Wind speeds
- Flight altitude- minimum and maximum

VI. Endangered species protection requirements

To protect endangered species, some products require Endangered Species Protection Bulletins that will contain geographically specific use limitations. Users will be directed to these Bulletins through a standard label statement. This statement may only be placed on a label after the completion of a risk assessment and determination that it is necessary. For complete endangered species labeling information, refer to *Chapter 11, Section IV, subsection J.*

VII. Miscellaneous statements

A. Point Source Discharge

For certain registered end-use products, technical grade products and other manufacturing use products, a "point source discharge" is a possibility because effluent from the manufacturing plant may contain pesticides. This does not include those products used to control roaches or other pests in the facilities, but applies to those chemicals used in the formulation processes.

The Agency recommends that the following National Pollutant Discharge Elimination System (NPDES) statement (as outlined in *PR Notice 93-10*) should appear on such products, in addition to any other required statements.

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA".

PR Notice 95-1 exempts certain end-use products (i.e., products in containers of less than 5 gallons (liquid), less than 50 pounds (solid, dry weight) and in aerosol containers of any size) from bearing effluent discharge statements specified by *PR Notice 93-10*. This policy applies to any pesticide product that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems. Such products include but are not limited to: (a) technical grade and manufacturing use products; (b) end-use products registered for industrial preservative, water treatment, or other industrial processing use such as in cooling tower water systems, pulp and paper mill water systems, secondary oil recovery injection water systems, food processing operations, leather tanning, and wood protection and textile treatment; and (c) large scale commercial and institutional end use (such as hospitals).

The exemption of certain containers from the labeling requirements of *PR Notice 95-1* does not relieve a producer or user of such products from the requirements of the Clean Water Act or state or local requirements, if applicable.

B. Seed Treatment or Granule/Pellet/Treated Bait Products

If a pesticide product contains directions for use in treating seed or is formulated as a granule, pellet, or treated bait, the Agency has historically required the following Environmental Hazards statements when appropriate:

> *"Treated _____[seed], [granules], [pellets], [baits] exposed on soil surface may be hazardous to _____[birds], [wildlife], [fish and aquatic invertebrates] or [birds, other wildlife, and fish]. Cover or collect _____[seeds], [granules], [pellets], [baits] spilled during loading".*

Revised September 2012

Label Review Manual

Chapter 9: Physical or Chemical Hazards

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I. Introduction

This chapter covers the Physical or Chemical Hazards statements that are required for certain pesticide products set out in the regulations, *40 CFR 156.78*. Such hazard statements address flammability, explosive potential and precautions. In addition, special hazard statements are required for certain fumigants. The reviewer should refer to the regulations and look through the guidance set out in the following sections to evaluate labels.

II. Placement of the physical or chemical hazards statement

Placement of the Physical or Chemical Hazards section should be immediately below the Hazards to Humans & Domestic Animals and Environmental Hazards statements in the Precautionary Statements section of the label. The physical or chemical hazards section must bear the subheading "Physical or Chemical Hazards".

III. Labeling for flammable products

Precautionary statements relating to product flammability are required if the product meets the criteria set out in the regulations and described below. Review Table 1 to determine the appropriate flammability statements.

A. Data Requirements for Flash Point/Flame Extension

Data requirements for flammability are covered in the regulations set out in *40 CFR 158.310* and *40 CFR 161.190*. OPPTS Harmonized Test Guidelines Series 830, Product Properties (830-6315), covers the **flash point** and **flame extension** of a product. The flash point is the lowest temperature at which a liquid product containing a combustible ingredient that gives off a flammable vapor will ignite. The flame extension test is required for aerosol products. The flame extension test is conducted by holding the aerosol can 6 inches from a flame and discharging the product across the flame. The extension of any flame from the flame source (typically a candle) in inches is noted and recorded. Any flame extension more than 18 inches or any flashback of flame to the valve at any degree of valve opening would then dictate the proper labeling of the product as either being flammable or extremely flammable. Flashback occurs when the flame is drawn back toward the aerosol can by the stream of propellant. This would indicate an extremely flammable product.

The product's flash point is shown on the Confidential Statement of Formula (CSF) and should be expressed in degrees Fahrenheit (°F) and the equivalent in degrees Celsius (°C). For aerosol products, the registrant is required to report the results of the flame extension

test and any positive flashbacks. This requirement does not apply to liquid products that are typically incombustible, as well as solid products not containing combustible ingredients such as most dust or granular formulations, pellets/tablets (baits), impregnated materials, etc. If the CSF indicates "not applicable" or "N/A for flammability", you may skip this section.

Table 1. Typical Statements for Flammable Products

Criteria	Required Text
(A) Pressurized Products	
Flash point at or below 20°F (-7°C) or if there is a flashback at any valve opening	**Extremely flammable.** Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F (-7°C)to 80°F (27°C) or if the flame extension is greater than 18 inches long at a distance of 6 inches from the flame	**Flammable.** Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized products	**Contents under pressure.** Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting
(B) Nonpressurized Products	
Flash point at or below 20°F (-7°C)	**Extremely flammable.** Keep away from fire, sparks, and heated surfaces.
Flash point greater than 20°F (-7°C) to 80°F (27°C)	**Flammable.** Keep away from heat and open flame.
Flash point greater than 80°F to 150°F (66°C)	**Combustible.** Do not use or store near heat or open flame.

[40 CFR 156.78]

B. Terms to Avoid

In order to avoid confusion with the product's overall signal word, the terms, CAUTION, WARNING, and DANGER (human hazard signal words based on toxicity data) are **NOT** to be used with the flammability statements. These words are only to be used as the human hazard signal word on the product. (*40 CFR 156.64(b)(3)*).

C. Total Release Fogger Products

If the product is a total release fogger containing a propellant with a flash point at or below 20°F, the following label statement must be included in the Physical or Chemical Hazards section:

"This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully".

In addition to this required language, a graphic symbol such as that illustrated below or an equivalent symbol must be displayed adjoining the Physical or Chemical Hazards statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word. Also, the two phrases shown below must be presented near the graphic symbol. (*PR Notice 98-6* and *40 CFR 156.78(d)(3)*).

Highly Flammable Ingredient
Ingrediente Altamente Inflamable

IV. Declaration of non-flammability

Certain products may bear a claim of non-flammability, with terms like: *"non-flammable"* or *"non-flammable (gas, liquid, etc.)"*. If the draft label has no claim of non-flammability, skip this section. However, if the proposed draft label has such a claim, the reviewer must check to see that the terms *"Extremely Flammable"* or *"Flammable"* do not appear in the Physical or Chemical Hazards section of the proposed label. Obviously, if either of these terms appears in the Physical or Chemical Hazards section, the claim of non-flammability CAN NOT be used.

A. Criteria for Declaring Non-Flammability

If the proposed label bears a claim of non-flammability, it should meet the following criteria:

1. **Gases/Mixtures of Gases.** If a gas or mixture of gases (under pressure), the product must not ignite when a lighted match is placed against the open cylinder valve.

2. **Liquids.** If a liquid, the product must have a flash point greater than 350°F (177°C). Refer to the CSF for the flash point.

3. **Pressurized Products.** Pressurized products (aerosols) may be classed as non-flammable if they meet the following criteria:

a. The flame extension is zero inches, using the method designated in the Guidelines.

b. There is no flashback.

c. The flash point of the non-volatile liquid component is greater than 350°F (177°C).

If you are unsure of whether the product meets the criteria for declaring non-flammability, submit the label package for product chemistry review to determine the validity of the non-flammability claim.

B. Non-Flammability Labeling Statement and Placement

The phrases *"non-flammable", "non-flammable gas"* or *"non-flammable liquid"*, may appear as a sub-statement to the ingredients statement, or on a back or side panel. The phrase should not be highlighted or emphasized (such as through use of inordinately large type size, or sharply contrasting color, etc.) so as to constitute a misleading safety claim.

V. Labeling for liquid products used near electrical equipment (*Dielectric Breakdown Voltage*)

If the proposed draft label is **not** for a liquid, skip this section. Some liquid products may pose a shock hazard when used near electrical equipment or outlets. The dielectric breakdown voltage is a measure of a liquid's capacity to conduct electricity and is required if the end use product is a liquid and is to be used near electrical equipment. (*40 CFR 158.310(d)*). (OPPTS Test Guidelines Series 830, Product Properties, #830-6321)

If the proposed label **is** for a liquid product, review the criteria below:

A. Criteria for Determining the Requirement of the Shock Hazard Statement

1. The use directions permit use of the product near electrical equipment or electrical outlets (transformers, cable TV pedestals, conduits, etc.); and

2. the data matrix does not provide a dielectric breakdown voltage; or

3. the dielectric breakdown voltage is less than 5,000 volts.

B. Shock Hazard Labeling Statement and Placement

The Agency has historically taken the position that if the product meets the criteria above; the following statement must be shown under the heading Physical or Chemical Hazards.

"Do not apply this product around electrical equipment due to the possibility of shock hazard".

VI. Labeling for explosive potential

A. When Required

When data submitted in accordance with *40 CFR Part 158* demonstrates hazards of a physical or chemical nature other than flammability (such as explosive potential), appropriate statements of hazard must be included on the label. Such statements must address the potential explosion hazard.

B. Chemicals with Potential Explosion Hazard

Chemicals that the Agency recommends have specific statements for potential explosion hazard include, but are not limited to:

- sulfur dust
- carbon dust
- potassium nitrate
- sodium nitrate
- potassium chlorate

If the CSF indicates that the product might require labeling for potential explosion hazard, submit the label package for product chemistry review for a determination.

VII. Additional label statements for certain fumigants

For some fumigant chemicals, statements of flammability or other physical or chemical hazards may be required. Several fumigants are highly flammable in the liquid or vapor form. The statements of flammability listed below for the following chemicals should be located on the side panel under the heading "Physical or Chemical Hazards". (*PR Notices 84-5* and *85-6*)

A. Sodium and Calcium Cyanides

"In the presence of moisture, highly poisonous gas (hydrogen cyanide) is formed".

VIII. Warning statements about mixing certain products

Some products react with certain surfaces such as galvanized steel to form highly combustible gases. Therefore, under the Directions for Use section, some product labels prohibit mixing, storing, or applying the product in galvanized steel or unlined steel containers. This is acceptable. However, no human hazard signal word (Caution, Warning, or Danger) may be used with this information. (*40 CFR 156.64(b)(3)*). The registrant may use "Attention", "Notice" or a similar word or phrase to alert the user. (Refer to chapter 11, Directions for Use "Compatibility with Other Products", for more information on this issue.)

IX. Requirements for use of fire retardant

Because of its combustion capability, the Agency has historically required all formulations of **sodium chlorate** to include an appropriate fire retardant chemical. Refer to *Chapter 5, Ingredients Statement, (IX)(I) Sodium Chlorate Products*, for placement instructions for the required statement.

X. Other physical/chemical hazard statements

When data submitted in accordance with the requirements set forth in *40 CFR 158.310* and *40 CFR 161.190* demonstrate hazards of a physical or chemical nature other than flammability or explosive potential, appropriate statements of hazard must be included on the label. Such statements may address hazards of oxidizing or reducing capability, reactivity, or corrosivity. For example, EPA has historically required a warning statement for oxidizing agents such as "Do not use with or store near any oxidizing or reducing agents." These decisions are made on a case-by-case basis. Check with other documents, such as REDs and registration review documents, to see if other wording is required.

Revised February 2016

Label Review Manual

Chapter 10: Worker Protection Label

National Garden Bureau

I. Introduction

This chapter provides guidance for reviewing statements required for the protection of occupational users of pesticides, including agricultural workers and handlers. While much of this chapter focuses on the requirements 40 CFR 156 (Labeling Requirements for Pesticides and Devices) Subpart K (Worker Protection Statements) designed to implement the protections of the Worker Protection Standard (WPS)(40 CFR 170), it includes protections required for non-WPS occupational users of pesticides as well. The portions of the label discussed in this chapter include the signal word, certain Precautionary Statements (Personal Protective Equipment (PPE), Engineering Controls, User Safety Requirements, User Safety Recommendations) and certain Directions for Use (Agricultural Use Requirements, Restricted Entry Intervals, Early Entry PPE, Notification Statements and Non-Agricultural Use Requirements). To the extent possible, label reviewers should ensure that all products with occupational exposure have appropriate risk mitigation measures equivalent to those measures contained in this chapter.

II. Background

Some substances and products may be excluded from FIFRA registration if they meet certain conditions or criteria. *40 CFR 152.6* sets out the following types of products that fall into this category.

A. The Worker Protection Standard

The Labeling Requirements for Pesticides and Devices, Worker Protection Statements (*40 CFR 156, Subpart K (156.200 -212)*) were published in *the Federal Register* on August 21, 1992, as was The Worker Protection Standard (WPS) (*40 CFR 170)*. Together these regulations establish standards and labeling requirements for worker protection. Further, *PR Notices 93-7* and *93-11* provide Agency guidance for complying with the WPS. The correct product specific WPS labeling can be found in the Acute Toxicity Data Evaluation Records (DER) for any given product.

B. Worker Risk Assessment

As part of the pesticide registration, reregistration, and registration review processes, a comprehensive worker risk assessment is performed. The worker risk assessment is based on toxicological criteria and potential for dermal, ocular, oral or inhalation exposure. Based on that risk assessment, worker protection labeling specific to the active ingredient is established. When necessary to address risk to non-WPS workers, the regulatory assessment document goes beyond the WPS to provide labeling protection for those workers not subject to the WPS. Chemical specific worker protection labeling requirements can be found in the regulatory assessment documents (Reregistration Eligibility Decision (RED), Registration Review Documents, etc.).

C. Evaluating the Regulatory Assessment Document and the Acute Toxicity Review

To determine the correct worker protection labeling for a given product, the label reviewer must consider the chemical specific worker protection labeling defined by the RED, the most current regulatory risk assessment document, and the product specific labeling defined in the acute toxicity review and/or guidance contained in this chapter. In most cases, the correct worker protection labeling is determined by taking the most restrictive statements from each source to derive the final handler PPE statements for the labeling.

III. Determination of products subject to the WPS

A. Scope of WPS

Review the criteria below to determine whether the label under review involves a product that is subject to the WPS. The WPS does not apply to manufacturing use products, or to unregistered pesticides used under an experimental use permit issued under *FIFRA section 5*, or under an exemption issued under *FIFRA section 18*. This determination is important because WPS products have unique labeling requirements. A summary table of the scope of WPS is also provided in Appendix A of this chapter to assist label reviewers in determining if a product is subject to WPS.

B. Criteria for Determining WPS Applicability

Does the product bear directions for use on an agricultural establishment (defined at *40 CFR 170.3* as "any farm, forest, nursery, or greenhouse") or involving the production of an agricultural plant (defined at *40 CFR 170.3* as "any plant grown or maintained for commercial or research purposes and includes, but is not limited to, food, feed, and fiber plants; trees; turf grass; flowers, shrubs; ornamentals; and seedlings"). See *40 CFR 170.102*. Or does the product bear labeling that could reasonably permit such a use?

NO, the product does not bear directions for use on an agricultural establishment or involving the production of an agricultural plant. The product is not subject to the WPS. The requirements in this chapter do not apply.

YES, the product does bear directions for use on an agricultural establishment or involving the production of an agricultural plant. Does the product meet any of the exceptions listed below?

Exceptions: The WPS contains exceptions for certain uses. WPS does not apply when any pesticide is applied on an agricultural establishment or involving the production of an agricultural plant in the following circumstances (*40 CFR 170.103*):

- For mosquito abatement, Mediterranean fruit fly eradication, or similar **area-wide public pest control programs** sponsored by governmental entities (area-wide programs are those where large swaths of public, private, residential, commercial and/or agricultural land/property is sprayed and a land owner has no control over

the spraying; this does not include the boll weevil and gypsy moth eradication programs or other similar program where specific areas of forests or agricultural land (e.g., cropland, Christmas tree nurseries, managed forests, etc.) are sprayed under arrangements with the land owner);

- On livestock or other animals, or in or around animal premises;
- On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses;
- On plants that are in ornamental gardens, parks, golf courses and public or private lawns and grounds, and that are intended only for aesthetic purposes or climatic modification;
- By injection directly into agricultural plants. Direct injection does not include "hack and squirt", "drill and spray", "chemigation", soil-incorporation, or soil injection;
- In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other non-crop areas, and non-managed pasture and rangeland use **(i.e., if the registrant wants to include directions for cutting hay in pastures or rangelands then the product must bear WPS requirements)**;
- For control of vertebrate pests around agricultural premises (vertebrate pest control applications for the purposes of crop protection is covered);
- As attractants or repellents in traps;
- Post harvest treatments on the harvested portions of agricultural plants or harvested timbers; and
- For research uses of unregistered pesticides.

If the product's directions for use allow for any uses that are not in the above exceptions, the product IS subject to the WPS. Keep reading.

If the product's directions for use contain only uses that fall under one or more of the above exceptions, the product is NOT subject to the WPS. The WPS-specific requirements in this chapter do not apply. Other non-WPS user protections, which may apply, are discussed later in this chapter.

1. **Exceptions for Seed Treatments:** The WPS does apply when pesticide products contain directions for use which allow treating seed at an agricultural establishment at or immediately before planting (such as through use of hopper boxes, planter boxes, slurry boxes, or tractor-mounted treaters). If seed treatment is only allowed off-farm (for example treating seed in a plant where seed is bagged to be used by growers) the WPS does not apply.

For further details, see *PR Notice 93-11, Supplement F*, and information at the following Website: (*www.epa.gov/sites/production/files/2015-06/documents/wps_interpretive_policy_06_26_15.pdf*)

Remember, in some cases it may not be clear whether or not a product is "within-scope" of the WPS if the product could be used on agricultural plants such as vegetables or ornamentals, but the registrant intends the product for an exempted use. **If the registrant's intention is to remove the product from the scope of the WPS, then clear language should be required on the label that limits or prohibits where this product can be applied (i.e., on WPS covered agricultural establishments), rather than who may apply it. This can be done by using exclusionary labeling statements such as the following:**

"Not for use in commercial or research nurseries or greenhouses",

or

"Not for use on agricultural establishments covered by the WPS (40 CFR Part 170)",

or

"Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes",

or

"For use only on residential lawns."

IV. Signal word

Products subject to the WPS that are classified as toxicity category I or II must also bear the corresponding Spanish signal word and the Spanish statement provided below. See *40 CFR 156.206(e)*. The Spanish signal word and statement below must appear in close proximity to the English signal word. The Spanish signal word for toxicity category I is "**PELIGRO**" and the Spanish signal word for toxicity category II is "**AVISO**". The statement that must appear on toxicity category I and II WPS products is as follows (the signal word Aviso and the statement are optional for toxicity categories III and IV):

"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"

V. Split labeling for WPS and non-WPS products

If a registered product contains uses that are both subject to WPS and not subject to WPS, the registrant should be encouraged to have separate registrations for each use type. However, the registrant is allowed to register the product with both use types on one label and/or choose to market the product with two sub-labels (under one registration) featuring only one of the use

types on each sub-label. The registrant may market the product under two distinctly different product labels, using additional brand names for the WPS labeling and non-WPS labeling. If the registrant chooses to market the product with both WPS and non-WPS uses, a Non-Agricultural Use Requirements box should be used to contain all non-WPS worker related restrictions. In either case, the registrant should submit a master label that clearly distinguishes between the two separate sub-labels. The registrant should not provide the WPS labeling merely as a supplemental label to a non-WPS product. See *PR Notice 93-7*.

Many pesticide products also contain residential consumer uses along with WPS and non-WPS uses. Because the personal protective equipment and other worker protection statements may be significantly different for occupational and residential consumer products, the registrant should be strongly encouraged to submit separate registrations with one containing the WPS and non-WPS uses, and the other containing the residential consumer uses.

VI. Precautionary statements

There are four types of worker protection statements that generally appear in the Precautionary Statements of a label. They are as follows:

A. Handler Personal Protective Equipment (PPE)

B. Statements for Contaminated PPE

C. Engineering Controls

D. User Safety Recommendations

Certain precautionary statements are required by Part 156 Subpart K (Worker Protection Statements (*40 CFR 156.200-212*) for products subject to the WPS. These statements may also be needed on non-WPS products if required by a regulatory assessment document. The reviewer should also refer to *Chapter 7* for additional, non-WPS, information on determining the correct toxicity category and other appropriate precautionary language.

A. Handler Personal Protective Equipment (PPE)

- **Determining the Correct Product-Specific PPE Requirements.** The correct handler PPE to be specified on the product labeling is determined by comparing the product-specific handler PPE requirements specified in the Acute Toxicity Review for a product with the chemical-specific handler PPE requirements specified in the regulatory assessment document. In most cases, the reviewer uses a combination of the most protective PPE requirements given in the regulatory assessment document and the Acute Toxicity Review to determine the correct handler PPE labeling statements.

  As noted above, the correct product specific handler PPE should be specified in the Acute Toxicity Review for a given product. The process used to derive the correct product-specific handler PPE is described in sections 1 through 4 below. In some cases the reviewer may need to use this process to determine the correct product-specific handler PPE labeling statements if the required handler PPE information isn't specified

in the Acute Toxicity review or if there are questions about the specified PPE requirements.

- **Compare Product-Specific PPE with PPE Required by the Regulatory Assessment Document.** After completing sections 1 through 4 below and identifying the correct handler PPE based on the product-specific acute toxicity data (or based on the Acute Toxicity Review), the reviewer should consider the handler PPE required by the regulatory assessment document for the active ingredient (such as a RED), if one has been published. A combination of the most protective PPE specified in the Acute Toxicity Review (or derived from sections 1 through 4 below) and the regulatory assessment document must be used to determine the appropriate product labeling. For guidance on which PPE is considered more protective, consult Table 7 below.
- Note: All end-use **occupational use products** (WPS or non-WPS) need to have the minimum baseline label-required work clothes for handlers consisting of long-sleeved shirt, long pants, socks and shoes. Technically these work clothes items are not considered PPE, but they can be required on labels (see 40 CFR 170.240 (b)).

1. **Identifying the Correct Product-Specific Handler Protective Clothing.** Once the correct toxicity category has been established, the product-specific handler PPE can be identified. Reviewers may obtain the correct product-specific handler protective clothing from the Acute Toxicity Review. Table 1 below shows how the correct product-specific handler protective clothing is derived in the Acute Toxicity Review based on the toxicity category for a given product.

Table 1. Handler PPE for WPS Products

Route of Exposure	Toxicity Category by Route of Exposure of End-Use Product			
	I DANGER	II WARNING	III CAUTION	IV CAUTION
Dermal Toxicity or Skin Irritation Potential[1]	Coveralls worn over long-sleeved shirt and long pants	Coveralls worn over short-sleeved shirt and short pants	Long-sleeved shirt and long pants	Long-sleeved shirt and long pants
	Socks	Socks	Socks	Socks
	Chemical-resistant footwear	Chemical-resistant footwear	Shoes	Shoes
	Waterproof or Chemical-resistant Gloves[2]	Waterproof or Chemical-resistant Gloves[2]	Waterproof or Chemical-resistant Gloves[2]	No minimum[4]
Inhalation Toxicity	Respiratory protection device[3]	Respiratory protection device[3]	No minimum[4]	No minimum[4]
Eye Irritation Potential	Protective eyewear[5]	Protective eyewear[5]	No minimum[4]	No minimum[4]

[1] If dermal toxicity and skin irritation toxicity categories are different, PPE shall be determined by the more severe toxicity category of the two. If dermal toxicity or skin irritation is category I or II, refer to Section 2 below to determine if additional PPE is required beyond that specified in Table 1

[2] Refer to Section 3, Table 3 to determine the specific type of waterproof or chemical-resistant glove.
[3] Refer to Section 4 to determine the specific type of respiratory protection.
[4] Although no minimum PPE is required for these toxicity categories and routes of exposure, the Agency may require PPE on a product-specific basis.
[5] "Protective eyewear" is to be used instead of "goggles" and/or "face shield" and/or "shielded safety glasses" and similar terms to describe eye protection, unless the assessment requires a specific type of eyewear for adequate protection.

2. **Identifying Additional Product-Specific Handler Protective Clothing (Apron and Headgear).** In addition to PPE listed in Table 1, additional, more protective PPE is required for products that are classified as toxicity category I or II for acute dermal toxicity or skin irritation. If the label under review does not involve a category I or II classification for either of these studies, skip this section. If the label under review does involve a category I or II classification for either the acute dermal toxicity or skin irritation, review Table 2 below to determine the additional product specific PPE.

Table 2. Additional Dermal Toxicity and/or Skin Irritation PPE For Toxicity Category I Or II (See *40 CFR 156.212(i)*)

Conditions Requiring Additional PPE and Labeling	Required PPE and Labeling
All products that are not ready-to-use and do not require a chemical-resistant suit must bear the corresponding statement:	"When mixing and loading wear a chemical-resistant apron".
All products labeled for application procedures that might involve overhead exposure must bear the corresponding statement:	"For overhead exposure wear chemical-resistant headgear".
All products labeled for use of equipment other than the product container to mix, load or apply the product must bear the corresponding statement:	"When cleaning equipment wear a chemical-resistant apron".

3. **Product-Specific Glove Selection for WPS Handlers.** The specific glove or gloves that are acceptable to meet the requirements for handler PPE must be listed on the label. See *40 CFR 156.212(f)*. Table 3, the EPA Chemical Resistance Category Selection Chart for Gloves, lists the types of waterproof or chemical-resistant gloves for products classified as toxicity category I, II, or III for acute dermal toxicity or primary skin irritation. See *40 CFR 156.212(e)*. It is EPA's current view that the Chemical Resistance Category Selection Chart for Gloves should not be placed or referenced on the product label. The chart is intended for EPA and registrant guidance only to determine the required glove type and glove statement for the label. Do not list the solvent category (A-H) on the product label.

   - **Determining the Correct Product-Specific Glove Requirements for WPS Handlers.** The correct glove type(s) to be specified on the product labeling for WPS-defined handler activities is determined based on the solvent in the product formulation. Table 4 below lists the solvent category for common solvents. The glove(s) selected must be rated as providing a "high" level of chemical resistance for the solvent category found

in Table 4 in order to be listed as an acceptable glove type on the product labeling for WPS handling activities.

Table 4 provides a listing of solvents that EPA believes are likely to be contained in pesticide products that are subject to the Worker Protection Standard. The appropriate chemical resistance category is listed for each solvent. IMPORTANT NOTE: If the chemical resistance category for a solvent is listed as "F or G", then the correct category is: "F" if the solvent constitutes less than 40 percent of the end-use product; or "G" if the solvent constitutes 40 percent or more of the end-use product. For those solvents not listed, the label reviewer should contact the Health Effects Division's Chemistry and Exposure Branch (CEB-I).

- **Glove Requirements for WPS Handlers for Products in Solvent Category A (Dry and Water-Based Formulations).** Products in solvent category A (i.e., those with dry or water-based formulations) DO NOT require chemical-resistant gloves. Waterproof gloves provide the necessary handler protection. For category A, listing of specific gloves types is not necessary. The correct glove statement for solid and aqueous-based product formulations in solvent category A is indicated below:

  (a) Solid Formulations: For those products which are applied as solids or formulated as solids and diluted solely with water for application, the glove statement shall specify: "**Wear waterproof gloves**". See *40 CFR § 156.212(f)(2).*

  (b) Aqueous-Based Formulations: For those products which are applied as formulated, and/or diluted solely with water for application, the glove statement shall specify: "**Wear waterproof gloves**" . See *40 CFR 156.212(f)(3).*

- **Glove Requirements for WPS Handlers for Products in Solvent Categories B – H (Other Liquid Formulations).** For all other liquid formulation products which are not aqueous-based, and applied as formulated or diluted with liquids other than water, (constitutes more than 5% of the end-use product), the glove statement shall direct users to wear the chemical resistant gloves specified, and the label statement shall specify **ALL** of the acceptable glove types from Table 3 that provide a **"high"** level of chemical resistance for the solvent category of the product in question.

  Based on Table 3, the correct glove statement for handlers for a product in solvent category B would be, "Wear butyl rubber or barrier laminate gloves". The correct glove statement for handlers for a product in solvent category H would be, "Wear barrier laminate or viton gloves". *40 CFR 156.212(f)(4).*

- **NOTE: It is important that ONLY glove types rated as providing a "high" level of chemical resistance for the product's solvent category found in Table 4 are selected as acceptable glove types for listing on the product labeling for mixing, loading, or application.**

- **NOTE: It is important that ALL glove types that provide a high level of chemical resistance for the solvent category be listed on the label as acceptable glove types so users have flexibility to select the most cost-effective glove option that will provide the required protection.**

- **Glove Requirements for WPS Handlers for Gaseous Formulations or Formulations Applied as Gases.** For products that are applied or formulated as gases, any existing glove statement established before 10/20/1992 including any glove prohibition statement will continue to apply. If no glove statement or glove prohibition currently exists on the label, then the glove statement shall be "wear nitrile or butyl rubber gloves". *40 CFR 156.212(f)(5)*

- NOTE: Registrants can specify a chemical-resistant glove type other than those specified in Table 3 if information is available that indicates that another glove type is more appropriate or provides greater protection. The registrant needs to justify why the alternative glove should be used. The label must indicate the specific type of chemical-resistant glove(s) that must be worn (for example, Wear nitrile or butyl rubber gloves; statement would be appropriate for the category of solvent). See *40 CFR 156.212(f)(1)*.

Table 3. EPA Chemical Resistance Category Selection Chart for Gloves

(For use when selecting glove types to be listed in the PPE section on pesticide label. Only select glove(s) that indicate a high level of chemical resistance.)

Solvent Category (see Table 4)	Barrier Laminate	Butyl Rubber ≥ 14 mils	Nitrile Rubber ≥ 14 mils	Neo-prene Rubber ≥ 14 mils	Natural Rubber* ≥ 14 mils	Poly-ethylene	Polyvinyl Chloride (PVC) ≥ 14 mils	Viton ≥ 14 mils
A (dry and water-based formulations)	high	high	high	high	high	high	high	high
B	high	high	slight	slight	none	slight	slight	slight
C	high	high	high	high	moderate	moderate	high	high
D	high	high	moderate	moderate	none	none	none	slight
E	high	slight	high	high	slight	none	moderate	high
F	high	high	high	moderate	slight	none	slight	high
G	high	slight	slight	slight	none	none	none	high
H	high	slight	slight	slight	none	none	none	High

*includes natural rubber blends and laminates
HIGH: Highly chemical-resistant. Clean or replace PPE at end of each day's work period. Rinse off pesticides at rest breaks.
MODERATE: Moderately chemical-resistant. Clean or replace within an hour or two of contact
SLIGHT: Slightly chemical-resistant. Clean or replace within 10 minutes of contact
NONE: No chemical-resistance.

NOTE: The EPA Chemical Resistance Category Selection Chart for Gloves should never be placed or referenced on the product label; it is intended for EPA and registrant guidance only.

Table 4. Solvent List (PRN 93-7, Supplement 2)

Solvent (chemical name or Trade name)	Chemical Resistance Category	Solvent (chemical name or Trade name)	Chemical Resistance Category
Acetone	B	Isopar L	E
Amyl Acetate	D	Isopar M	E
Aromatic 100	F or G	Isopar V	E
Aromatic 150	F or G	Isophorone	B
Aromatic 200	F or G	Isopropanol	C
Aromatic Petroleum	F or G	Kerosene	E
Butoxypolypropylene glycol	C	Methanol	C
Butyl acetate	D	Methyl amyl ketone	B
Cyclohexanone	B	Methyl Carbitol	C
Diacetone alcohol	C	Methyl isobutyl ketone	B
Diethanolamine	C	Mineral oil	E
Diesel fuel	E	Mineral spirits	E
Dipropylene glycol monothylether	C	Naphtha	E
Ethanol	C	N-methyl pyrrolidone	B
Ethylene glycol	C	Penreco 2251 oil	E
Exxon 589	E	Petroleum Distillate (aliphatic)	E
Heavy Aromatic Naphtha	F or G	Petroleum oil	E
Hexylene glycol	C	Propylene glycol	C
Isopar B	E	T 500-100	F or G
Isopar C	E	Tetrahydro-furfuryl alcohol	C
Isopar E	E	1,1,1-Trichloroethane	H
Isopar G	E	Water	A
Isopar H	E	Xylene	F or G
Isopar K	E	Xylene range solvents	F or G

4. **Product-Specific Respiratory Protection Device (RPD) Selection for Handlers.** RPD(s) are required for all products classified as toxicity category I or II for acute inhalation. See *40 CFR 156.212(g)*. Review the RPD types in Table 5 and determine if the label lists the appropriate type based on the product description and toxicity category. If the registrant has submitted information showing that a more protective RPD should be selected, allow the registrant to retain that RPD requirement on the label under review. Information that could support an alternate RPD could be the submission of the product vapor pressure data indicating that the RPD specified in Table 5 would not provide adequate protection or could pose an increased risk to the user.

   In June 1995, the National Institute for Occupational Safety and Health (NIOSH) revised the certification criteria and definitions for nonpowered, air-purifying particulate respirators. *42 CFR Part 84* replaced the outdated certification standards in 30 CFR Part 11 regulations.

The Part 84 regulation created a total of nine classes of particulate filters; these classes apply only to nonpowered, air-purifying, particulate filter respirators.

Table 5. Respirator Language

Pesticide Type	Vapor Pressure (mmHG)	Respirator Language	
		Oil in Application Mix	No Oil in Application Mix
Non-Organic Gaseous Products: Products that are formulated or applied as a gas that are not organically based such as phosphine	**1 x 10^{-3} or lower**	**Case by case basis**	**Case by case basis**
Organic Gaseous Products Used in Enclosed Areas: Products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas must bear labeling specifying the following RPD requirements and statement	1 x 10^{-3} or lower	For handling activities in enclosed areas, use either a NIOSH approved supplied-air respirator with NIOSH approval number prefix 19C; or a self-contained breathing apparatus (SCBA) with NIOSH approval number prefix TC-13F.	For handling activities in enclosed areas, use either a NIOSH approved supplied-air respirator with NIOSH approval number prefix 19C; or a self-contained breathing apparatus (SCBA) with NIOSH approval number prefix TC-13F.
Organic Gaseous Products Applies Outdoors: products that are formulated or applied as a gas (space and soil fumigants) and that may be applied outdoors must bear labeling specifying the following RPD requirements and statement:	1 x 10^{-03} or lower	A NIOSH-approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC-84A; or NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC-14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter, with NIOSH approval prefix TC – 23C.	A NIOSH-approved respirator with an organic vapor (OV) cartridge with a combination N, R, or P filter with NIOSH approval number prefix 84A; or NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC 23C.
Solid Products: Products that are formulated and applied as solids.	NA	A NIOSH approved particulate respirator with any R or P filter with NIOSH approval	A NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number

		number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.	prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.
Liquid Products in Toxicity Category I: Products that are formulated or applied as liquids:	Lower than 1 x 10^{-05}	A NIOSH approved particulate respirator with an R or P filter with NIOSH approval number prefix TC – 84A. ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.	A NIOSH approved particulate respirator with any N, R, or P filter, NIOSH approval number prefix TC-84A . ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.
	Greater than 1 x 10^{-05}	A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC – 84A; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC-23C; or a NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 14G.	A NIOSH approved respirator with an organic vapor (OV) cartridge with any combination N, R or P filter with NIOSH approval number prefix TC – 84A; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC-23C; or a NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 14G.
Liquid Products in Toxicity Category II: Products that are formulated or applied as liquids	Lower than 1 x 10^{-04}	A NIOSH approved particulate respirator, with any R or P filter with NIOSH approval number prefix TC-84A. ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.	A NIOSH approved particulate filter with any N, R, P filter with NIOSH approval number prefix TC-84A. ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.
	Greater than 1 x 10^{-04}	A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter,	A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination N, R or P filter with NIOSH approval

		with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC – 23C.	number prefix TC – 84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC – 14G; or powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC – 23C.

(a) Selection Criteria. In determining whether a pesticide product label should require the use of non-oil resistant N-series, oil-resistant R-series, or oil-proof P-series respirators the reviewer should first examine the CSF for the presence of oil compounds in the product formulation at any concentration. NIOSH defines oil as a high boiling-point, liquid hydrocarbon that will accumulate on a respirator's particulate filter with minimal evaporation. This includes any of a large class of substances which are viscous, combustible, liquid at ordinary temperatures, and soluble in ether or alcohol but not in water. Some examples of oil-type products or products that contain oil are: mineral oils (e.g., petroleum/hydrocarbons lubricating oils), as well as certain adjuvants such as crop oils and surfactants added when a pesticide product is mixed with water or with other pesticides in tank mixes. If an oil is present at any level in the pesticide itself or in the mixture of pesticide with water, solvent, fertilizer, adjuvants, etc. added to the crop, and if a respirator is required (i.e. if the product is in toxicity category I or II for inhalation toxicity), then only an R- or P-series respirator may be used; an N-series respirator may only be used when there is no oil involved. See *PR Notice 98-9*.

Generally, N-series are only used for non-oil based aerosols. R-series may be used for oil based aerosols with a time limitation of 8 hours, and P-series for periods of time longer than 8 hours with considerations of resistance, soiling, or damage. The reviewer should then examine the Directions for Use section of the label for instructions calling for the addition of crop oils, surfactants and other organic substances that may be oils as defined by NIOSH. If the reviewer has any question whether a substance listed in either the CSF or the Directions for Use is actually an oil, this question should be referred to the product chemistry reviewer.

(b) Respirator types for which label language changes are not required at this time. The following are types of respirators which are NOT subject to change per *PR Notice 98-9*:

- Powered air purifying respirator equipped with a high efficiency particulate air (HEPA) filter (NIOSH approval number prefix TC-21C).

- Powered air purifying respirator equipped with an organic-vapor (OV) removing cartridge plus a high efficiency (HE) filter (NIOSH approval number prefix TC-23C).
- Powered air purifying canister-type respirator (gas-mask) equipped with an organic vapor canister that incorporates HE filters (NIOSH approval number prefix TC-14G).

Table 6. Oil Resistance and Efficiency of Filters

Filter Efficiency	N-series particulate filters Not resistant to oil.	R-series particulate filters Oil-resistant.	P-series filters Oil-proof.
95%, 99%, and 99.97%	N95/ N99/ N100 Not resistant to oil. May be used for solid & liquid particulate hazards. *Time limitations*: Use and reuse of N-series filters would be subject only to considerations of hygiene, damage and increased breathing resistance. (See manufacturer's recommendations, and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	R95/ R99/ R100 Oil-resistant. May be used for solid & liquid particulate hazards. *Time limitations*: The R-series filters should be used only for a single shift (or for 8 hours of continuous or intermittent use) when oil is present. (See manufacturer's recommendations, and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	P95/ P99/ P100 Oil-proof May be used for solid & liquid particulate hazards. *Time limitations*: Use and reuse of the P-series filters would be subject to the manufacturer's recommendation Repeated exposures may degrade the filter below its rated efficiency. (See manufacturer's recommendation and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).

Table 7. Guide to Selecting the Most Protective Handler PPE Level of Protection

Type of PPE	Minimum Required	Next Highest Level of Protection	Next Highest Level of Protection	Highest Level of Protection
Protective Clothing	Long-sleeved shirt and long pants	Coveralls over short-sleeved shirt and short pants	Coveralls over long-sleeved shirt and long pants	Chemical Resistant Suit
Protective Footwear	Socks and Shoes	Chemical - resistant footwear	Chemical-resistant boots	NA
Gloves	None	Waterproof or Chemical-resistant gloves	NA	NA
Protective Headwear	None	Chemical-resistant headgear	NA	NA
Chemical resistant Apron	None	Chemical-resistant apron worn over long-sleeved shirt and long pants	Chemical-resistant apron worn over coveralls over long-sleeved shirt and long pants	NA
Respiratory Protection Device	None	Particulate filtering facepiece respirator[1]	Respirator with a vapor removing cartridge or canister with a particulate prefilter[2]	Air Supplying Respirator

[1] Can be used only for filtering particulates: it is not adequate if vapor pressure indicates a vapor-removing filter is needed.
[2] Can be used when it is necessary to filter both particulates.

5. **Required Location for Handler PPE.** Handler PPE statements for applicators and other handlers must appear in the PRECAUTIONARY STATEMENTS section of the labeling in the "HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)" section. See *40 CFR 156.212(c)(1)*.

6. **States May Require the Use of Additional PPE.** The Agency will approve additional state-required language if it is clear that it applies only in that state.

B. Statements for Contaminated PPE

The statements for contaminated PPE must appear in the PRECAUTIONARY STATEMENTS section of the labeling. The preferred location is directly below the Personal Protective Equipment. Remember to check the regulatory assessment document, if one has been completed, for specific User Safety and PPE requirements such as engineering controls. All occupational use products must bear the following statements:

"Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry".

If the product is a concentrate (diluted before use, or is an ultra-low-volume or low-volume concentrate, or contains more than 50% active ingredient) and is in Toxicity Category I or II, its label must include the following statement before the previous statement:

"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them".

C. Engineering Controls

Engineering Controls (eg. closed systems, enclosed cabs, lock and load containers) may be required by the regulatory assessment document or by the Acute Toxicity profile of a given product. The following statement should appear on the label in the Precautionary Statement section unless supplemented or superseded by a regulatory assessment document:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS".

1. **For Toxicity I and II Products packaged in water soluble package.** If a product is in Toxicity Category I or II (signal word Danger or Warning) for either acute dermal toxicity or skin irritation potential, then the following statements shall appear on the label unless supplemented or superseded by a regulatory assessment document:

   "Water-soluble packets, when used correctly, qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves.

   [insert "NOTE" here that would be added to any WSP engineering control statement that specifies the correct use (mixing/loading) procedures that must be followed for a WSP product to be allowed closed system status.]

   IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down".

2. **For Toxicity III and IV Products Packaged in Water Soluble Packages or other similar devices (e.g., gel packs).** If a product is in Toxicity Category III or IV for acute dermal toxicity and skin irritation potential, or if either of these data are not available, and signal word is CAUTION, then the following statements may appear on the label unless supplemented or superseded by a regulatory assessment document:

"Water-soluble packets, when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, and socks instead of listed PPE.

[insert "NOTE" here that would be added to any WSP engineering control statement that specifies the correct use (mixing/loading) procedures that must be followed for a WSP product to be allowed closed system status.]

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down".

D. User Safety Recommendations

If the product falls within the scope of WPS, then a User Safety Recommendations box, as indicated in *PR Notice 93-7, Supplement Three*, must also appear in a separate box on the label containing appropriate user safety information. Many regulatory assessment documents also require User Safety Recommendations for Non-WPS occupational use products. Although the registrant may include any appropriate user safety recommendations on their label, below are some typical statements required by the regulatory assessment documents or found on many products.

Example of a User Safety Recommendations Box showing sample language:

"User Safety Recommendations"

"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing".

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing".

VII. Directions for use

For products subject to the WPS, there are four types of worker protection statements that generally appear in the Directions for Use of a label. They are as follows:

A. Required Statements;

B. Agricultural Use Requirements Referral Statement for Supplemental Labeling;

C. Agricultural Use Requirements Statement; and

D. Statements for Products with both WPS and Non-WPS Uses.

A. Required Statements

The following statements must appear on all WPS labels near the beginning of the Direction for Use section of the labeling under the heading Agricultural Use Requirements. See the sample at the end of this chapter.

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application". (For wide-area treatments, see the additional language presented in section C (2) below 40 CFR 156.206(a).

"For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation". 40 CFR 156.206(d).

B. Agricultural Use Requirements Referral Statement for Supplemental Labeling

This statement should be used if you put the Agricultural Use Requirements Box in Supplemental Labeling. It must appear on the product label near the statement referring users to the supplemental labeling and must be placed IN A BOX under the heading AGRICULTURAL USE REQUIREMENTS.

"Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to supplemental labeling under "AGRICULTURAL USE REQUIREMENTS" in the DIRECTIONS FOR USE section for information about this standard".

C. Agricultural Use Requirements Statements

1. **Required Statements.** The following statements must also appear on all labeling for all WPS products. These statements must appear after the heading "Directions for Use" and IN the AGRICULTURAL USE REQUIREMENTS box. See example *AGRICULTURAL USE REQUIREMENTS box* at the end of this chapter.

   "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170.

   "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label (in this labeling) about (use any of the following that are applicable) personal protective equipment, restricted-entry interval, and notification to workers." 40 CFR 156.206(b)(2).

2. **Restricted Entry Statements.** An REI is the time period immediately following a pesticide application during which entry into the treated area is restricted. REIs can be

determined by referencing Supplement Three-A of *PR Notice 93-7*, the regulatory assessment document or by using the guidelines listed below. If the REI established by the regulatory assessment document is different from the guidance below, the REI established by the regulatory assessment document must be required on the label. Some labels may have several different REIs for different crops. The label must include the following statement under the "AGRICULTURAL USE REQUIREMENTS" heading (*40 CFR 156.208(a)*):

"Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) (include single REI here, see below for multiple REIs)".

(a) Single REI: If a product has only one REI, then the REI shall appear as a continuation of the above required sentence in one of the following formats:

"of X hours"; "of X days" or "until the acceptable exposure level of X ppm or mg/m3 is reached." 40 CFR 156.208(b)(1).

(b) Crop- or use-specific REI(s): If different REI's exist for crops or uses, then the REI must appear in the directions for use for that crop or use. The REI must be immediately preceded or followed by the word "*Restricted Entry Interval*" or the letters *"REI". 40 CFR 156.208(b)(2).*

(c) 72-hr REI for organophosphorous ester in arid areas: If the active ingredient is an organophosphorous ester that may be applied outdoors in an area where the average annual rainfall for the application site is less than 25 inches per year, the following statement shall be added to the restricted-entry statement: 72 hours in outdoor areas where average annual rainfall is less than 25 inches a year. *40 CFR 156.208(c)(2).*

3. **Early Entry PPE.** All products subject to the WPS should bear the following statements for workers who reenter the treated area prior to the expiration of the restricted entry interval:

"For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear:"

(a) Start with the Handler PPE;

(b) Omit any respiratory protective devices;

(c) If the handler body clothing requirement is a long-sleeved shirt and long pants, then the early-entry worker requirement shall be "coveralls", and

(d) If there is no hander requirement for gloves, then the early-entry requirement shall be *"chemical resistant gloves (made of any waterproof material)*".

4. **Notification-to-Workers Statements.** Notification to workers statement is required if the product meets the criteria below:

   (a) **Fumigants**: Fumigants that are registered for use in greenhouses or whose labeling allows use in greenhouses must bear the following statement:

   "For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse".

   (b) **All Other Products**: Products which contain any active ingredient classified as toxicity category I based either on acute dermal toxicity data, skin irritation data, or the criteria below shall bear the following notification statement:

   "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas".

   To identify the toxicity category follow the steps below:

   Step 1: Examine available data for toxicity category determination. Since acute dermal and skin irritation data may not always be available, use the following list in selecting which data/signal word should be used for determining the acute toxicity category:

   a. Consider acute dermal and skin irritation data for all active ingredients (a.i.(s)) in the product;

   b. If acute dermal data are missing for any a.i., consider acute oral data for that a.i. in addition to the primary skin irritation data on the a.i.

   c. If acute oral and acute dermal data are missing for any a.i., consider the skin irritation data on the a.i.;

   d. If the acute oral, acute dermal, and skin irritation data are missing for any a.i., consider the signal word of the registered manufacturing use product for the a.i.;

   e. If none of the above data is available for any a.i. in the product, consider the signal word of the end-use product.

   Step 2: If any data used in Step 1, items a-e are toxicity category I or otherwise require use of the equivalent signal word of "DANGER", then a notification statement is required.

   (c) Location of Statement. All notification statements must be located in the DIRECTIONS FOR USE section in the box with the heading AGRICULTURAL USE REQUIREMENTS. If notification is not required (because the product meet the toxicity criteria or is not a fumigant), the reviewer should make sure that the statement about notification to workers is not included in the Agricultural Use Requirements box.

D. Statements for Products with both WPS and Non-WPS Uses

If the label contains only uses within the scope of the WPS, skip this section. If the label contains or the regulatory assessment document requires entry restrictions, notification requirements, or other instructions similar to WPS requirements that apply to uses NOT within the scope of the WPS (non-agricultural uses), there should be a second box on the label called: Non-Agricultural Use Requirements.

This box may be placed anywhere in the Directions for Use section of the label after the Agricultural Use Requirements box and must contain the following statements (*PR Notice 93-7, Supplement 3*):

> *"Non-Agricultural Use Requirements*
>
> *The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses".*

In addition, place into the Non-Agricultural Use Requirements box all the entry restrictions, notification requirements, or other statements and instructions (except personal protective equipment requirements) that apply to the non-WPS uses on the label. Examples: "Keep children and pets out of the treated area until sprays have dried"; or, "Keep unprotected persons out of treated areas until sprays have dried".

VIII. Determining the correct REI

The correct REI may be specified in the regulatory assessment document. If a regulatory assessment document is not available, refer to Supplement Three-A of *PR Notice 93-7*, or use the following guidance to determine the correct REI.

A. REI(s) For Fumigants

Current REI(s) will be retained or at the time of registration, an REI will be determined on a case-by-case basis.

B. REI(s) Determined by Subdivision D Data

REI(s) will be retained.

C. All Other REI(s).

Follow the steps below to determine the correct REI(s).

Step 1: Identify Acute Toxicity Data to Be Used in Determining REI(s). REI(s) are based on the most severe acute toxicity category assigned to the acute dermal, eye irritation and skin irritation data for all of the active ingredients (a.i.) in a product. In many instances, these data are not always available. The following list indicates the preferred order for selecting data on which to determine the toxicity category for each a.i.:

1. Use the acute dermal, eye irritation and skin irritation data for the technical product for each active ingredient;
2. Use the acute oral and eye irritation and/or skin irritation data for any active ingredient missing acute dermal data;
3. Use the eye irritation and/or skin irritation data for any active ingredient missing the acute oral and acute dermal data;
4. Use the signal word of the registered manufacturing use product that is the source of the active ingredient which does not have any acute oral, acute dermal, eye irritation, or skin irritation data;*
5. Use the signal word of the product under review if none of the above data is available on the active ingredient and if the active ingredient without data is not a registered manufacturing use product.*

The following chart provides examples of how the acute toxicity category is determined for purposes of determining the REI.

Table 8. Determining Acute Toxicity Category for REI Purposes

Product A	Variable Acute Tox Data for Each Active Ingredient	Tox Cat.	Tox Cat. Used to Determine REI
single a.i.	Acute dermal tox data Eye irritation data	III II	II[1]
Product B	**Available Acute Tox Data for Each Active Ingredient**	**Tox Cat.**	**Tox Cat. Used to Determine REI**
a.i. #1	Acute dermal tox data Eye irritation data Skin irritation data	III II III	II
a.i. #2	Acute oral tox data	III	III
a.i. #3	Signal word of registered MP (source of a.i.)	I	I[2]

[1] The appropriate REI for Product A would be 24 hours.
[2] The appropriate REI for Product B would be 48 hours.

Step 2: Determine appropriate REI(s) using the chart below and note exceptions:

Table 9. Determining the REI (See 156.208)

Most Severe Tox Category Usedto Determine the REI	Length of Required REI
When the most severe tox category is III or IV	The REI is 12 hours
When the most severe tox category is II	The REI is 24 hours
When the most severe tox category is I	The REI is 48 hours
In addition: If the product is an organophosphate ester that inhibits cholinesterase and may be applied outdoors in an area where the average rainfall for the application site is less than 25 inches per year.	The REI is 72 hours

Exceptions:

1. If any existing interim REI, established prior to 10/20/1992, is longer than the REI(s) shown in the table above, the existing interim REI should be retained.

2. If a product bears REI(s) for uses not subject to the WPS, those REI(s) should be retained and included in the "Non-Agricultural Use Requirements" box. If multiple REI's exist, follow instructions for multiple REI's below.

3. If a product is reduced risk, the REI may be 4 Hours. To qualify for a reduction in the REI to 4 hours products must meet the following criteria:
   (a) The active ingredient is in Toxicity Category III or IV based upon data for acute dermal toxicity, acute inhalation toxicity, primary skin irritation, and primary eye irritation. Acute oral toxicity data are used if no acute dermal data are available. If EPA lacks data on primary skin irritation, acute inhalation, or primary eye irritation of the active ingredient, the Agency can review data on that end-point for similar active ingredients (analogs), as long as it excludes such active ingredients from consideration for the reduced REI, if the analog is in Toxicity Category I or II for that endpoint.

   (b) The active ingredient is not a dermal sensitizer (or in the case of biochemical and microbial active ingredients, no known reports of hypersensitivity exist).

   (c) The active ingredient is not a cholinesterase inhibitor (N-methyl carbamate and organophosphate) as these chemicals are known to cause large numbers of pesticide poisonings and have the potential for serious neurological effects.

   (d) No known reproductive, developmental, carcinogenic, or neurotoxic effects have been associated with the active ingredient. If the active ingredient does not have data available for these chronic health effects, EPA considers data on appropriate chemical and biological analogs. Active ingredients that have been classified as carcinogenic in Group B (probable human carcinogen) or Group C (possible human

carcinogen) chemicals for which quantification of potential risk (Q1*) is appropriate, as well as those scheduled for the Health Effects Division's Cancer Peer Review process, are omitted from consideration.

(e) EPA does not possess incident information (illness or injury reports) that are "definitely" or "probably" related to post-application exposures to the active ingredient.

(f) The active ingredient has not been the subject of a Reregistration Eligibility Decision (RED) document or other risk assessment which concluded that a longer REI was necessary to protect workers. Active ingredients with REIs established during reregistration activities are NOT eligible for reduced REIs.

4. It should also be noted that WPS does not apply to pheromones used in insect traps.

IX. Labeling statements for special situations

A. Chemigation Statement (from *PR Notice 93-7*, Supplement 3, page 39)

Does the current labeling for an end-use product contain instructions for posting a warning sign about chemigation?

NO: No action is necessary.

YES: Find those statements in your revised labeling and add the following statement:

"This sign is in addition to any sign posted to comply with the Worker Protection Standard".

B. Soil Incorporation/Injection (from *PR Notice 93-7*, Supplement 3, page 39)

Does the current labeling for an end-use product contain instructions for incorporating or injecting the product into the soil or planting medium?

NO: No action is necessary.

YES: Include the following statement in the Agricultural Use Requirements box under Item 4 which gives the restricted entry interval instructions:

"Exception: if the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated".

C. Engineering Control Statements (from *PR Notice 93-7*, Supplement 3, page 50)

If the current product labeling or risk assessment does not contain any requirements or recommendations for the use of closed systems, enclosed cabs, or open or enclosed cockpits, then the following paragraph may be added to the labeling:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS".

1. To add this statement to your labeling, include it in the Precautionary Statements section of the label under the heading "Engineering Controls".

D. ULV and LV Uses (from *PR Notice 93-7*, Supplement 3, page 40)

If the product contains directions for use as a ULV or LV concentrate, do the following:

1. If the product does not have any PPE requirements, do nothing.
2. If the product does have PPE requirements and the product contains directions for use ONLY as a concentrate, do the following:

   In the Precautionary Statements section, change the standard heading of "Mixers and Loaders must wear:" to:

   "Mixers, loaders, applicators, and other handlers who may be exposed to the concentrate must wear:" This heading will also replace the standard heading "Applicators and other handlers (other than mixers and loaders) must wear:"
3. If the product does have PPE requirements but does not contain directions for use solely as a concentrate, do the following:
   (a) In the Precautionary Statements section, change the standard heading of: "Applicators and other handlers (other than mixers and loaders) must wear:" to "Handlers who may be exposed to the dilute through application or other tasks must wear:" AND
   (b) Change the standard heading *"Mixers and Loaders must wear:"* to "Handlers who may be exposed to the concentrate through mixing, loading, application, or other tasks *must wear*:"

X. Sample agricultural use requirements box

Directions for use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State and Tribe, consult the State/Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this `label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of___hours. The REI is 72 hours in outdoor areas where average annual rainfall is less than 25 inches a year.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants
- chemical-resistant gloves
- chemical-resistant footwear plus socks
- protective eyewear
- chemical-resistant headgear

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

APPENDIX A. Summary Table of the Scope of WPS

CRITERIA	Subject to WPS?
Product is a manufacturing use product, or an unregistered pesticide used under an experimental use permit issued under *FIFRA section 5*, or under an exemption issued under *FIFRA section 18.*	NO
Product bears directions for use on an agricultural establishment or involving the production of an agricultural plant (defined at *40 CFR 170.3* as any plant grown or maintained for commercial or research purposes and includes, but not limited to, food, feed, and fiber plants; trees; turf grass; flowers, shrubs; ornamentals; and seedlings). Or the product bears labeling that could reasonably permit such a use.	YES
EXCEPTIONS: The use sites below are not subject to WPS	
Mosquito abatement, Mediterranean fruit fly eradication, or similar area wide public pest control programs sponsored by governmental entities.	NO
Use on livestock or other animals, or in or around animal premises.	
Plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses.	
Plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds, and that are intended only for aesthetic purposes or climatic modification.	
Use by injection directly into agricultural plants. Direct injection does not include "hack and squirt", "frill and spray", "chemigation", soil-incorporation, or soil injection.	
In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other non-crop areas, and pasture and rangeland use. Note if the registrant wants to include directions for cutting hay in pastures or rangelands then the product must bear WPS requirements.	
Control of vertebrate pests.	
Use as attractants or repellents in traps.	
Post harvest treatments on the harvested portions of agricultural plants or harvested timbers.	
Research uses of unregistered pesticides.	
Commercial seed treatment that is only allowed to be conducted off-farm. (e.g. Seed treated at factories that are placed in containers/bags.)	

Revised December 2014

Label Review Manual

Chapter 11: Directions for Use

USDA NRCS

I. Introduction

This chapter outlines the basic elements of the Directions for Use portion of the label and provides a review strategy for ensuring that this information is presented in a clear, concise and effective manner.

II. Purpose of directions for use

The Directions for Use portion of a pesticide label describes how the product can legally be used and how the product must not be used. The specific requirements for the directions for use section are found in the regulations at *40 CFR 156.10(i)*, but in general the information necessary is as follows:

- the site(s) where the product can be used
- the pest(s) that the product can be used to control;
- the application methods that are required or preferred;
- how much pesticide can be applied and the rate of application;
- whether there are any restrictions on use for factors such as weather, time of day, season of the year, contamination of sensitive areas, exposure of nontarget species, etc.;
- the application methods that are prohibited;
- how often the pesticide should or can be applied;
- maximum application rates (per treatment and per year);
- all restricted entry intervals (REIs) pertaining to existing uses, as applicable;
- preharvest intervals (PHIs); and
- any other requirements for safe effective use of this product, as necessary.

Special Reminder to Reviewers

The Directions for Use section should provide basic application information. Further, any applicator, and especially the general consumer, who is a non-technical and occasional applicator, should be able to easily understand and be expected to follow the directions for use.

The directions for use reflect the Agency's determination that the use of the product in such a manner does not cause unreasonable adverse effects on the environment under FIFRA. The Directions for Use section should be organized and carefully worded so that the directions are understood by the person expected to use or to supervise the use of the pesticide. Sentences

should be written to indicate whether any actions are mandatory or advisory. Other sentences in the use directions may be used only to convey background information.

III. Enforceability of directions for use

When writing and reviewing labels it is critical to distinguish the statements that are intended to be enforceable from those that are included for informational purposes. *If you aren't able to distinguish the difference, applicators and enforcement agents won't be able to either.* The registrant should be required to clarify the intent of any unclear statements on the label. Use of the following list will help to eliminate some common enforceability problems in the Directions for Use portion of labels:

- **Any direction or precaution that is necessary to achieve effective, safe use of the product must be stated in mandatory terms (e.g., must, will, do not)** Do not allow the use of terms such as "can", "should" or "may" if the statement is intended to be mandatory. See *PR Notice 2000-5* and *Chapter 3* of this manual for more information on mandatory versus advisory language.
- **Any direction that is not truly necessary for effective, safe use of the product, or which is too vague or subjective for a user to clearly follow**, must NOT be stated in mandatory terms. Such informational or advisory statements should be factual and provide a reason for the desired behavior, as described in Chapter 3 discussion of mandatory versus advisory language.
- **Use terms with specific definitions whenever possible.** Terms that are defined in FIFRA, by Federal Agencies, or give clear instruction are preferable. For example, terms such as "near", "around", and "windy" do not have clear definitions and may cause confusion. A clear statement, such as "in winds strong enough to move spray away from treatment area", would be preferable to "windy". To define a soil type use of USDA standard terminology, such as "sandy loam", is appropriate. (For soil classifications see *http://websoilsurvey.nrcs.usda.gov/app/* or *Soil Properties: Texture*)
- **Clearly separate advisory and mandatory statements.** Intermingling advisory and mandatory language can cause confusion and make the intent of the statement(s) or an entire section unclear. If separation is not practical, the intent of each statement as mandatory or advisory needs to be clear.
- **Ensure that section headings are appropriate to all material contained beneath it**. For example, if a heading includes the term "recommended", everything in that section must be intended to be purely advisory and need not be followed for safe and effective use of the product. If we believe a statement is necessary for proper use, the term "recommended" would not be accepted.

- **"For Use Only by" statements should not be approved unless it refers to a group that can be clearly defined by FIFRA, an applicable regulation or an EPA policy which has defined an identifiable group of users—such as persons licensed by the state for termite control** (*PR Notice 96-7*) or employees of mosquito control agencies (*PR Notice 2005-1*). For example, statements such as "For professional use only" or "For commercial use only" do not have accepted definitions, and the apparent "limitation" is meaningless and unenforceable, and may be considered misleading.
- **Avoid "avoid".** The term "avoid" poses particular problems. The Agency views the term as mandatory, however it also recognizes that some users may perceive the term as advisory, or may see it as a weaker statement than the clear prohibition of "do not". Reviewers should strongly discourage the use of the word "avoid" for this reason.

IV. Review strategy for directions for use

This section presents strategies for reviewing the Directions for Use section of pesticide labels. It provides a list of key questions that reviewers must ask as they review the label. It also discusses some common problems and issues that reviewers face when reviewing the Directions for Use section.

A. General Strategy for All Labels

1. **Charts, Tables, and Formats.** Labels should be presented so they are easy to read and understand by the user. The *Consumer Label Initiative (CLI)* research, as well as other label research done around the world, shows that in many cases graphics (charts, graphs, symbols, or pictures) can be used to help convey information and may be useful in the Directions for Use portion of the label. However, care needs to be taken that the graphics do not contain or imply false or misleading information and they provide accurate information in a clear, concise and complete manner.

   Subheadings, like paragraph headings in a book, help to organize the information and also make it easier to find. Information presented in a "bulleted" format is easier to read and understand than longer narrative paragraphs, even when the same type size is used. When more lengthy and complicated information is required, a tabular format may be easier to follow.

   Due to the variety in size and shapes of labels, not all format recommendations may work on all labels; however, consideration should be given to them whenever feasible. Products labels must remain consistent with applicable statutory and regulatory requirements.

   The following are some suggested formats:

   (a) Bulleted Format. When using the bulleted approach, the intent is not to leave information out, but to make it visually easier to follow. Either partial, or complete, sentences can be used. Any type of character could be used as the "bullet".

Example of Bulleted Format:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Precautions

- Use may damage marble surfaces.

Restrictions

Do not apply to porous surfaces

Application Instructions

- Turn nozzle to "Spray" or "Stream".

For Cleaning:

1. Hold nozzle 6-8 inches from surface.
2. Spray soiled area.
3. Wipe clean
4. For surfaces in direct contact with food, a rinse is required.

To Control Mildew:

1. Pre-clean surface
2. Spray until thoroughly wet.
3. Let air dry
4. Repeat weekly or when new growth appears.

To Disinfect:

1. For heavily soiled surfaces, pre-clean according to Cleaning Directions.
2. Spray until thoroughly wet.
3. Let stand 10 minutes before wiping or rinsing.

(b) Modified Paragraph Format. The modified paragraph format presents text in a series of full sentences, like the old standard narrative format, but includes subheadings and numbering to make it easier to locate information. If a paragraph format must be used, it is helpful to the reader to include either subheadings, or to highlight key words/phrases. The language should be simple and use correct grammar and punctuation.

Examples of Modified Paragraph Format:

Application Instructions:

BROCCOLI (PHI) : **Pests**; **Application Method(** Spray, Broadcast); **Dose** (amount per unit area); **Type of Equipment** (Sprayer, Aircraft, Spreader); **Timing** (Spring, Foliar, Pre-plant, Pre-plant Incorporated); **Application Intervals; Phytotoxicity** concerns as it applies to timing and method of application; **Restrictions** (Grazing, haying, maximum dose per application, maximum dose per crop cycle or per year, maximum number of application per year.). **Other comments** which apply to this site. **CAULIFLOWER**.....

FOR HOUSEHOLD USE: SHAKE WELL BEFORE EACH USE. Apply to surfaces only. Hold container upright 12" from surface and spray. Spray until surfaces are wet. Over wetting asphalt tile, rubber and plastic materials may cause damage. Repeat treatment as necessary, but no more than once a week. **ROACHES, CRICKETS, SILVERFISH, SPIDERS**: Spray directly on insects when possible. Thoroughly spray cracks, baseboards, underneath kitchen shelves, and other places where insects live. **ANTS, EARWIGS**: Spray door sills, wood frames, outside foundations and porches. Spray directly on ant hills. **FLIES, MOSQUITOES, GNATS, WASPS**: Apply on screens, walls, door and window frames, and other surfaces where insects congregate.

(c) **Tabular Format.** When the label is in a tabular format make sure that all the appropriate information is included, that it is easy to follow, and that types of information are clearly divided or discernible.

2. **Answer Key Questions.** The questions contained in the *Label Reviewer's Checklist* (Appendix A) should be addressed when reviewing the Directions for Use section of the label. When answering these questions the reviewer should refer, as appropriate, to the references mentioned below under section IV. A. 2.

   The reviewer must not assume that because a registrant claims to be modifying only one part of this section that the rest of the directions for use are acceptable even though the label has been accepted in the past. A complete review is advisable because:

   - Some labels may be very old.
   - Previously accepted uses and language may no longer be recommended.
   - Agency guidance such as PR Notices may have been updated or clarified.

   Therefore, the entire Directions for Use section needs to be reviewed very carefully before accepting the label.

3. **Consult Essential Document References.** Various policy documents including Pesticide Registration Notices provide guidance on particular issues. Label reviewers should use the guidance along with the applicable laws to make case-by-case determinations on the acceptability of label language. In addition, reviewers should consult:

   - Applicable documents and guidance policies for the active ingredient(s) including: Registration Review Decision documents, Reregistration Eligibility Decisions (RED, IRED, TRED) Biopesticide Registration Action Documents (BRAD), Science assessments, etc.
   - Applicable product-specific data evaluation records and assessments,
   - Labels of substantially similar or identical products,
   - The Registration Standard (if there is one not superseded by a RED),

- For new or revised uses, available science/technical reviews, or the efficacy reviewer,
- The *40 CFR, Part 180* for published tolerances supporting food/feed uses, and
- Current Pesticide Registration (PR) Notices.

Table 1. Toxicity Categories

Crop	Phi	Target Pests	Rate	Special Directions
Broccoli For use only in California, Oregon, and Washington Do not apply within X days of harvest	Do not apply within X days of harvest	Aphids Flea beetles Leafhoppers Whiteflies	X fl. oz in X gal of water (diluent) by ground or X gal of water (diluent) by aircraft	**Method of Application** Spray, Broadcast, Chemigation, Ultra Low Volume. **Equipment** Sprayer, Sprinkler Irrigation, Mist Sprayer, Spreader. **Timing** Foliar, Pre-plant, Post-plant, Post-harvest, Dormant. **Application Interval** Can be X-X days as needed. No more than X times per year. **Notes:** (applying to a specific pest)
		Armyworms Lygus bugs	X fl. oz in X gal of water (diluent) by ground or X gal of water (diluent) by aircraft (*different than above*)	*Same as above but with different timing, pre-plant incorporated including a different type of equipment*
		Limitations: 1. Do not apply more than X fl. oz. of Product per acre per application 2. No more than X gallons per acre per year. 3. Make no more than X applications per year. Note; Gallons or applications "per season" is NOT acceptable by itself without a "per year" statement. There may be more than one growing season per year for some crops; EPA needs a hard number for risk assessment. **Grazing Restrictions:** Describe grazing restrictions here NOTES: Information on phytotoxicity, pest resistance, or other comments that apply to the site.		

Pesticide Registration (PR) Notices are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies,

procedures and regulatory decisions. PR notices are important resources to help the label reviewer stay informed about current regulatory policies in OPP. These documents are available at: *Pesticide Registration (PR) Notices | Pesticides | US EPA*.

If a Reregistration Eligibility Decision (RED) Document has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that:

- All of the use sites on the label are in Appendix A of the RED (or have been evaluated and approved by OPP in a subsequent regulatory document);
- The site(s)/pest(s) are all eligible for Reregistration; and
- If any of the uses have been declared ineligible for reregistration, the use may not be reregistered.

Further, if the product contains more than one active ingredient, *all uses* on the label must be acceptable for *all* of the active ingredients. If there is more than one a.i. in the product and a RED is available for each, all sites on a label must be listed in each RED.

4. **Consult Subject Matter Experts.** The "Directions for Use" portion of a label can become very complex depending on the number of sites, pests claimed and application methods. If a label seems to present problems of clarity, organization, enforceability or consistency with EPA policy, reviewers should seek advice.

   Reviewers should first consult PM/team leaders or efficacy reviewers. PM/team leaders may raise more difficult questions to their branch chief, or, in cases of "mandatory or advisory" issues or other enforceability questions, may directly contact staff in the Office of Enforcement and Compliance Assurance for advice.

   At the discretion of branch chiefs, or PM/team leaders, label questions may be forwarded to OPP's Label Committee, which includes representatives of OPP's registering divisions, plus PRD, FEAD, OGC and OECA. Other authorities or sources of information may be consulted as appropriate such as commodity groups, State FIFRA Issues Research and Evaluation Group (SFIREG), or Regional offices of EPA.

5. **Identify the Intended User.** Although this information generally will not be stated specifically on the label, it is very important to keep the intended user of the product in mind when reviewing any pesticide label. For example, if the product is primarily intended for use by general consumers or "residential/household users" the application sites listed on the label should be appropriate for use on or in and around the home, yard, and garden, or on pets. Such sites might include, home flower or vegetable gardens, ornamentals (shrubs and trees), home lawns, or residential greenhouses. Note that "residential use" which defines the use site rather than the person applying the product is defined in regulation at 40 CFR part 152.3

The phrases, "*For use only by (a certain type of user)*"; "*For Commercial Use Only*" or "*For Professional Use Only*" should not appear on a product label. Such statements are often used by registrants solely for marketing purposes, however, neither FIFRA nor the applicable regulations provide for labeling statements such as for "professional use", "commercial use", "industrial use" or other such terms. The registration process does not involve a determination that a product should be used, for example, only by "service persons". Such statements are vague and they can mislead customers into believing that a product with such a statement is somehow more efficacious than another product. Furthermore, such statements are also not likely to be enforceable under FIFRA.

Note that it is allowable to say "intended for use by (type of user), but not with the word "only". "Intended for use" statements are recognized by state regulators as advisory and not enforceable. The terms "maintenance applicator" and "service technician" are defined in FIFRA section 2 (jj) and (kk) respectively, but these terms do not seem to be in use by pesticide registrants. Several specific user groups that can be identified as the only allowable users for non-RUP products in certain situations are described in Section V. D, E and F of this chapter.

The Agency can designate pesticides for "restricted use" if the Agency determines that the product may cause unreasonable adverse effects without additional regulatory restrictions. (*FIFRA 3(d)*, see also *40 CFR Part 152 Subpart I*). In that case, a restricted use product can only be sold to and used by a certified applicator. (The regulations at *40 CFR Part 171* set out the requirements for certification of applicators.)

It should be noted that although some of the above mentioned statements restrict *who* can **use** the product, none of the statements restrict who may **purchase** the product, unless the pesticide is classified for restricted use. The only way to restrict sale of the product is through classification of the product as a Restricted Use Pesticide, as described in *Chapter 6*. Therefore a label statement that includes a "not for sale to (type of person)" is not acceptable if the product is not classified for restricted use.

6. **Clarity.** The text in the Directions for Use section should be expressed in complete sentences unless a bulleted format is used in a chart. These sentences should be direct and to-the-point, while covering all necessary information. Directions should be expressed as clearly and concisely as possible. Long or complicated paragraphs of narrative instructions should be avoided wherever possible. The label reviewer should direct registrants to alter any text which appears to be incorrect, confusing, or contradictory to other label statements. If the reviewer knows what the registrant intends to write (or what EPA permits to be written) on a particular matter, the reviewer can draft corrected text. If the label reviewer cannot determine the registrant's intent, the reviewer should identify the area of concern for the registrant, explain the problem with the information, and inform the registrant that revised text is needed to meet FIFRA standards.

EXAMPLE: Consider the following statement taken from the Directions for Use section of a pesticide product's label:

"Mix 1/2 to 2 pints of (pesticide) in 100 gals. of water. Apply 100 to 200 gals. per acre depending on spray equipment and tree size".

It is not clear to what the language "Apply 100 to 200 gals per acre..." refers. Does it refer to undiluted product, or does it refer to the diluted spray solution? Is the applicator to simply add more water to a 100-gallon spray mix to cover larger trees or to use twice as much of spray solution mixed as directed by the first sentence?

Assuming that the "100 to 200 gals." refers to diluted spray mix, improved instructions would be:

"To make spray solution, mix 1/2 to 2 pints of this product in 100 gals. of water. Apply 100 to 200 gals. of diluted spray solution per acre to trees depending on tree size and the coverage obtained with the spray equipment used".

7. **Errors in the Directions for Use.** If an error is discovered in the Directions for Use portion of the cited, registered label, the reviewer must take the time to contact the registrant about the error(s) and request that the registrant submit a corrected label within a suitable time frame such as 30 days. If there are risk issues associated with the error, the Agency can issue an order under Section 6 or 13 limiting the time by which the registrant can sell the existing stocks.

B. Identical or Substantially Similar Product Application Label Review of Directions for Use

If the application is for a product identical or substantially similar to another (see *Chapter 4*), reviewing the directions for use is fairly straightforward: The label reviewer should make a side-by-side comparison of the proposed set of use directions to the use directions on the label for the registered product(s) which are identified in the identical or substantially similar application. Because only one source may be listed on the confidential statement of formula for 100% repacks, the label may not vary in meaning from the source product label.

Target pests or use sites found on the registered product's label may be omitted from the identical or substantially similar product's labeling. For example, an identical application is made for an insecticide formulation to add structural perimeter treatments for crickets, ants, and sowbugs. The registered product referenced in the identical application must be labeled for this site, and its label must claim crickets, ants, and sowbugs; although other species (earwigs, millipedes) also may be claimed on the registered label. While the pending submission need not have all the pests listed on the registered label, no *new use sites or pests* may appear on the label for the pending identical or substantially similar product. The format for the presentation of use information on the identical or substantially similar label need not be identical to the format on the registered (cited) label as long as the critical

information as described above remains the same and the identical product meets applicable legal requirements on labeling.

Note: Be aware of the possible presence of an unacceptable use or other error on the label of the cited registered product when doing side-by-side comparisons. Follow-up with appropriate product manager, if mistakes are found.

C. Not Identical or Substantially Similar Label Review of Directions for Use

When a registrant's application is not for an identical or substantially similar product as when a registrant proposes a new use, new application rate, preharvest interval (PHI) change, or another action not previously approved by the Agency, a more extensive review than the simple comparison is necessary. Such applications usually must be accompanied by relevant data and/or data citations, and should be sent for technical review. The "Directions for Use" on the proposed label may need to be altered due to the outcome of the science/technical review (i.e., use rates on crops, PHIs, reentry intervals, restrictions such as bee hazard warning statements, application rates and methods may have to be added or modified). The use rate, or application rate, may be the most difficult part of this section to interpret and review. Application rates and number of applications per season for agricultural products may be affected by the residue data submitted or cited by the registrant. Approval of most agricultural uses requires that an appropriate tolerance be established because of the pesticide chemical residue on food.

V. Additional review strategies for specific products

A. Manufacturing-Use Product (MP)

If the pesticide is an MP intended only for use by formulators preparing end-use products, the directions for use on the label may be greatly reduced in scope. See regulation at *40 CFR 156.10(i)(1)(iii)*. However, these products must still have the following:

1. "Directions for Use" heading;

2. Misuse Statement(s);

3. The statement "For Formulation Into A (type of pesticide)" followed by a continued statement of the uses (crops/sites or other uses) for which the end-uses product (EP) may be registered and uses for experimental purposes that are in compliance with FIFRA.

   Any MP registrants wishing to do so may add one of the following statements to an MP label under "Direction for Use" to permit the reformulation of their product for a specific use or all additional uses supported by a formulator or user group:

(a) *"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s)".*

(b) *"This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s)".*

MPs intended for formulation into end-use pesticides (EPs) should not also be labeled for end uses for several reasons:

- Unique Environmental Hazards statements are required for MPs,
- Personal Protective Equipment (PPE) is not specified by the Agency for MPs,
- In some cases, only limited Directions For Use are required for MPs,
- Use Classification is not appropriate for MPs, and
- WPS labeling, if applicable to end uses, would not be appropriate for MPs

Labeling which specified both pesticide manufacturing use and end use would require different, sometimes conflicting, label statements, in these and possibly other areas of the label and may result in user confusion and/or misuse of the product.

Pesticide products used for manufacturing products which are not required to be registered (i.e., treated articles or substances that qualify under 40 CFR 152.25(a)) are considered to be end-use products. Labels for such source products must bear complete Directions for Use sections.

Also, the Agency has allowed EPs to be used as an active ingredient source for other EPs if the purchased source of the active ingredient is registered for the same (or more) use patterns (i.e., sites, rates, timing, etc.) as the reformulated product.

B. Typical End-Use Pesticide Products

The Directions for Use for typical end-use products may appear on the container label and/or may be securely attached to the packaging as long as the container label makes reference to the attachment with a statement such as *"See directions for use on enclosed brochure"*, as long as the reviewer has determined that it is not necessary for such directions to appear on the container label. (see *40 CFR 156.10(i)*)

The manner in which information is conveyed in the Directions for Use section of many pesticide labels varies greatly from label to label. Within categories of pesticides, specific formats for the Directions for Use section may have been implemented through specific regulatory actions on products. Such formats take precedence over the general information presented in this section, but not over the requirements of *40 CFR, 156.10(i)*. As a result, the starting point for analysis of directions for use for end use products is the regulations.

For typical end-use products, the Directions for Use section will cover the following standard requirements, such as:

- the misuse statement, Worker Protection Standard boxes, etc.
- lists of permitted use sites;
- lists of target pests for which control is claimed;
- restrictions and other limitations on use;
- general information about the product and its use
- specific application instructions
- "Storage and Disposal" instructions

C. Experimental Use Permits

In general, the directions for use on experimental use permit labels must follow the same label requirements as products registered under FIFRA Section 3. The directions for use must be consistent with section G of the permit. The label reviewer should ensure that the site, pests, and application method on the submitted label match those listed in their permit. Refer to *Section III.(I) of Chapter 4* for more information on Experimental Use Permits.

Under the Directions for Use heading and after the use classification statement (if required), the statement to be used for Experimental Use Permits (EUPs) (*40 CFR 172.6(a)(1)*), reads as follows:

"For Experimental Use Only".

This statement should also be prominently displayed on the front panel. An example of statements that are often included prominently on the front panel of the experimental use permit labels is provided below:

"For Experimental Use Only

For use only at an application site of a cooperator or participant and in accordance with the terms and conditions of the Experimental Use Permit. Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Permit program. This label must be in possession of the user at the time of pesticide application. For use in the following states only: (insert states listed on permit)".

D. Pesticide Product Intended for Use Only By Physicians, Veterinarians or Pharmacists

Directions for Use sections on labels for products of these types may be very limited in content. However, this provision applies only when the product is also classified as a drug

and regulated as such under the provisions of the *Federal Food, Drug and Cosmetic Act (FFDCA)* (see *40 CFR 156.10(i)(1)(iii)(B)(3)*).

If the product is intended for use only by veterinarians, then the label must state that the product can only be used by veterinarians or physicians. The following statement is an acceptable one to meet this requirement: *40 CFR 156.10(i)(1)(iii)(B)*.

> *"This product may only be used by veterinarians/physicians".*

E. Termiticides

Most currently registered termiticide products are not classified for restricted use, but contain label statements limiting their use to commercial applicators. If the product is a termiticide that is not classified as restricted use, then the Agency has historically taken the position that the label should contain the following statement:

> *"For use by individuals/firms licensed or registered by the state to apply termiticide products. States may have more restrictive requirements regarding qualifications of persons using this product. Consult the structural pest control regulatory agency of your state prior to use of this product".*

Termiticide products already classified for "Restricted Use" will remain so classified and must bear the required restricted use statements on product labeling. Consult *PR Notice 96-7* for further guidance on termiticide labeling.

F. Adult Mosquito Control Products

If the product is an adult mosquito control product, applications should be limited to trained personnel. (See *PR Notice 2005-1*.)

> *"For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision".*

VI. Standard elements

All standard elements and language required by FIFRA and the applicable regulations to appear in the Directions for Use must be placed on the label in the locations specified for them if FIFRA or applicable regulations do specify a location; however, not all elements have such a specified location. These elements should be presented on the label:

- "Directions For Use Heading"
- Use Classification Statement

- Misuse and Related Statements
- Worker Protection Standard (WPS) Requirements (if applicable)
- I Instructions and Information Subheading (if applicable)
- Use Restrictions (if applicable)
- Chemigation Information (If applicable)
- Spray Drift Language (if applicable)
- Endangered Species Statement (if applicable)
- Storage and Disposal Statements

A. Directions for Use Heading

The heading of the Directions for Use section of the label must be "***Directions for Use***". **It may not have any other title.** Headings such as "General Directions", "Use Directions", "Recommendations for Use", "Recommended Uses", "How to Use", or any other similar wording are not acceptable.

The heading "Directions for Use" may be capitalized, put in bold type, and/or underlined to give it proper emphasis. The heading must be of such prominence and placement on the label that it is clear that all subsequent components of the section fall under the main heading "Directions for Use". Such prominence can be assured by putting the heading in the largest, most conspicuous type that is used in the section and by centering the heading on the label panel while left-justifying all subheadings within the section.

B. Use Classification Statement

If a product is classified as restricted use the label must bear the phrase *"Restricted Use Pesticide"* under the heading "Directions for Use". *40 CFR 156.10(i)(2)(i)*. The phrase "Restricted Use Pesticide" must meet the minimum type size requirements of the human hazard signal words. *40 CFR 156.10(j)(2)(i)*. Consult Chapter 6 of this manual for further guidance on restricted use pesticide label requirements.

C. Misuse Statement

Experimental Use Permits and all registered pesticides, including all end-use and manufacturing use products, must bear labeling which has the following statement immediately below the Use Classification:

> *"It is a violation of Federal law to use this product in a manner inconsistent with its labeling".*

Other statements relating to misuse, such as those listed below, are acceptable for residential/ household use products. These additional statements can appear on the label following the required general misuse statement mentioned above:

"STOP! Read the label before using".

"Use only as directed on this label".

"Read label very carefully, including any special requirements which pertain to your growing area".

"Failure to follow all precautions and directions is illegal".

D. Worker Protection Standard (WPS)

The Worker Protection Standard (WPS) regulations (40 CFR Part 156, subpart K) require certain statements on the labeling of all pesticide products within the scope of the WPS. Required WPS statements should appear after the general misuse statement under the heading Agricultural Use Requirements (40 CFR 156.206). WPS statements generally include the subheadings General Statements, Restricted Entry Interval (REI), Notification to Workers Statements and Non-agricultural Use Requirements.

The following statements must appear on all WPS labels near the beginning of the Direction for Use section of the labeling under the heading Agricultural Use Requirements.

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application". (For wide-area treatments, see section 3c below under Directions for Use)

"For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation".

Chapter 10 provides the information necessary to determine whether the label under review is subject to the requirements of the WPS and specifies how the WPS requirements must be presented on the label.

E. Instructions and Information Subheading

Labels may include a section concerning instructions that explain how the product works and provide information that is applicable to all the use sites and pests listed on the label.

F. Use Restrictions

Non-site- specific precautions, restrictions or limitations of the product comprise another important type of use restriction information in the Directions for Use section. Such a restriction may consist of an imperative sentence—practically any sentence that begins with

a verb and ends in a period—or any other sentence which requires or forbids certain action (See Section III of *Chapter 3* for discussion of mandatory labeling statements). Use restrictions may also be phrased as requirements by using words such as "must", "never", and "always". Any precautions and restrictions that apply to specific site(s) and pest(s) must be included in the directions specific to that combination. Use restrictions may be required by the Agency to meet the unreasonable adverse effects standard or proposed by the registrant or applicant. Such restrictions may include, but are not limited to, the following categories:

- User Restrictions;
- Rate Restrictions or Limitations;
- Site, Pest, Timing, Weather, Soil, Geographic Restrictions;
- Equipment, or Application Method Restrictions;
- Miscellaneous Precautions such as Staining, Phytotoxicity, Incompatibility with Other Products, etc.; and
- PHIs or Rotational Crop Restrictions (unless site-specific).

1. **Appropriateness of Precautions and Restrictions.** The reviewer must carefully assess each restriction or limitation to make sure that it does not place on the product obligations that the user cannot reasonably carry out.

   For example, an aquatic herbicide for use in ponds and lakes might have a restriction like:

   "POTABLE WATER: Delay the use of treated water for domestic purposes for a period of three weeks or until such time as an approved assay shows that the water contains no more than 0.1 ppm (herbicide active ingredient)".

   Because any number of applicators could be using the product in public ponds or lakes used by many households or municipalities, the applicator may have no reasonable way of complying with such a restriction. Either another risk mitigation measure must be developed, or the product should be given restricted use status.

   Some proposed labels will contain various use restrictions desired by the registrant, (e.g., "Do not tank mix this product with [their competitor's products]," or "Do not use this product for formulating into other products," or other similar restrictions). Unless there is some risk based reason for such use restrictions, such statements are not acceptable on product labels because they are false and/or misleading. Labels may prohibit use of the product on certain crop varieties based on risk or efficacy concerns.

   When used in reference to the response of crops and weeds to the proposed pesticide product (e.g., an herbicide label), registrants should use the word "tolerant" instead of

"resistant". For example, the label should refer to the use of the product on herbicide *tolerant* crops, not herbicide-resistant crops.

2. **Use-Related Restrictions.** Any other appropriate information (precautions or restrictions) should be presented in the restrictions subsection unless such statements apply only to some of the uses permitted by the label, in which case the statements belong with directions for specific site and pest groupings. Use related information can include restrictions regarding the timing of application, weather, soil conditions, geography, or other relevant considerations. This information should be appropriate for the intended user(s), site(s), and pest(s) listed on the label.

3. **Use Limitations for Specific Ingredients.** The label reviewer needs to check the Confidential Statement of Formula to determine if peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, Crustacean, or wheat commodities are listed. The reviewer should be aware that the presence of these common food allergens in pesticide products limits the acceptable use sites and application methods found in the directions for use. If the product contains these ingredients, evaluate label use directions for compliance with *40 CFR 180.1071*.

G. Resistance Management Labeling Considerations

The Office of Pesticide Programs (OPP) of the EPA has developed voluntary pesticide resistance management labeling guidelines based on target site/mode of action (MOA) for agricultural uses of herbicides, fungicides, bactericides, insecticides, and acaricides. MOA refers to the biochemical mechanism by which the pesticide acts to control the pest and should not be interpreted to imply that these chemicals share a common toxicological mechanism for purposes of cumulative human health risk assessment under FIFRA and the Federal Food, Drug, and Cosmetics Act (FFDCA).

Rotation of MOA action was selected as a primary pest/pesticide resistance management strategy for this voluntary regulatory initiative rather than metabolic resistance, because it is the easiest for reducing the likelihood of resistance, especially monogenic resistance, and it will help reduce the likelihood of resistance caused by other mechanisms. The rotation of MOA is a scientifically-sound, flexible, and practical resistance management strategy. Other management practices that will reduce resistance include application timing, crop rotation and other cultural practices, and application equipment cleaning. The voluntary resistance management guidelines based on rotation of MOA are found in *Pesticide Registration Notice 2001-5*. These guidelines were developed under the auspices of the North American Free Trade Agreement (NAFTA) by both the U.S. and Canada. Canada published similar guidelines to those of the U.S. in October 1999 as *Regulatory Directive 99-06*. Both countries agreed that uniform labeling guidance across North America would encourage adoption of resistance management strategies and help reduce the development of pest resistance.

In support of these goals, the resistance management guidelines based on rotation of MOA provide guidance to users about pesticide classes and pesticide management strategies. Adoption of these guidelines will provide users with easy access to information regarding target site/mode of action resistance.

The objective of the voluntary resistance management labeling guidelines (*PR Notice 2001-5*) is to include pesticide mode of action symbols and resistance management recommendations on the labels of all new and existing pesticide products for agricultural uses. The management of pesticide resistance is an important part of sustainable pest management and this, in conjunction with alternative pest management strategies and Integrated Pest Management (IPM) programs, can make a significant contribution to reducing pesticide risk to humans and the environment. When used, the mode of action (MOA) numerical classification symbol(s) are recommended to be placed in the upper right hand corner of the front-panel of end-use product labels, although the numerical classification symbol can be placed elsewhere on the label. The numerical MOA classifications are found in the Appendices of PR Notice 2001-5. A sample of this is:

GROUP	**1**	**HERBICIDE**

In addition to the MOA classification symbols, a registrant may choose to have resistance management statements on the label. If used, these statements should be included in the "Use Directions" for end-use products for the control of weeds, plant pathogens (diseases), insects and mites under the heading "Resistance Management Recommendations". These statements should be clearly distinguished from mandatory statements (see *PR Notice 2000-5*, "Guidance for Mandatory and Advisory Labeling Statements") on the pesticide label to avoid confusion to the users.

Pesticide Registration Notice 2001-5 provides examples of standard resistance management labeling statements that focus on the following areas: (1) avoid repeated or sequential use of products in the same MOA class through rotation of MOA; (2) if tank mixes or premixes are legally allowed, makes sure each compound is from a different MOA class; (3) use an effective IPM program; (4) monitor for loss of product performance; (5) contact your extension specialist, certified crop consultant, or manufacturer for the latest resistance management information; and (6) contact the pesticide producer to report loss of efficacy. Alternatively, registrants may supply their own resistance management labeling statements that address these same areas. Registrants may also choose to have specific mandatory statements regarding resistance management, but these statements would not fall under "Resistance Management Recommendations".

H. Chemigation Information

Review of labels for agricultural uses, nursery uses, uses on golf courses, sod farms or in greenhouses should be conducted with reference to the guidance contained in *PR Notice 87-1* (chemigation), unless the product is solely for residential use, direct injection into plants,

post-harvest application, or is applied as a gas or solid (pellets, tablets, granules, or dusts). Subject labels (as specified above) must either include labeling statements regarding chemigation contained in PR Notice 87-1 or the statement:

"Do not apply this product through any type of irrigation system".

Any product used on agricultural sites that may be applied by chemigation should contain information such as the following:

- Types of irrigation systems to be used;
- Consequences of improper chemigation;
- To whom questions about chemigation can be directed;
- Warnings against connecting irrigation equipment to public water supplies without safety mechanisms;
- Personnel required for adjustment of chemigation equipment;
- Statements required for Toxicity Category I products.

Note *PR Notice 87-1* contains the complete wording of all the chemigation text categories indicated above. Check relevant REDs for any chemigation text specific to the active ingredient(s) in the product under review.

I. Spray Drift Labeling

Generic label language for Spray Drift prevention is still pending. In the meantime, OPP is developing spray drift management label language on a case-by-case basis. Typically, risk from potential spray drift, based on the use patterns for any given product will be identified in the risk assessment. The label reviewer should check the relevant RED or reregistration documents for required spray drift language as well as work with the risk assessors to craft appropriate spray drift risk mitigating label language.

J. Endangered Species Label Statement

To address Endangered Species Act and FIFRA obligations, some products are required to carry a statement informing the user of potential risk to endangered species. This language will generally be required only after the Agency has created an Endangered Species Protection Bulletin (Bulletin) following EPA's determination, informed by an endangered species risk assessor, that additional use restrictions are necessary to address risks to listed species. The Bulletins will contain all necessary information to convey the use limitations. Because compliance with these Bulletins will be a requirement of product labeling, any restrictions in the Bulletins will be enforceable under FIFRA.

If EFED, AD or BPPD has determined that a product requires endangered species labeling, EPA will request that the registrant amend its labeling to place the following statement at the

beginning of the Directions for Use section under the heading "ENDANGERED SPECIES PROTECTION REQUIREMENTS:"

> *"This product may have effects on endangered species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult* http://www.epa.gov/espp/ *or call 1-800-447-3813. You must use the Bulletin valid for the month in which you will apply the product".*

This statement is intentionally generic and cannot be altered by staff absent the approval of senior OPP management. No geographically specific endangered species statements can appear on the label in conjunction with this statement, as it specifically references Bulletins. If geographically specific endangered species information appears on the labeling as a means of addressing the risks to listed species, EFED, AD, or BPPD should be notified as appropriate so they may incorporate any such geographically specific information into the referenced Bulletins.

VII. Where the product is issued

All application or treatment site(s) must be identified on the label and clearly associated with the pest controlled. Many labels identify such sites near the beginning of the use directions (e.g., in the "Use Restrictions" subsection) and/or in the text presenting specific application directions.

A. Consistency of Listed Sites

Wherever the sites are listed on the label, they must be consistent with sites listed elsewhere on the label. For example, if the front panel lists ornamentals as a site, then the directions for use must include the appropriate treatment directions for ornamentals.

B. Complete Site Information

Treatment sites must be clearly identified. For example, if residential sites are listed as an application site, exactly where the pesticide is applied must be specified, for example, bathrooms or kitchens. Reviewers should require the use of the most specific site terminology reasonable. If possible, refer to site indices in OPPIN to identify appropriate site terminology but avoid the use of site categories (e.g., "domestic dwellings") that would be awkward or confusing on a label. The use of uniform site terminology is useful for the purposes of exposure reviews. The label reviewer may need to inform the registrant that the application sites need to be identified more specifically, for example, cracks and crevices in kitchen areas of residences instead of "dwellings".

C. Site Groupings

If the use site is indicated by a broad crop grouping, such as "ornamentals," the registrant should be instructed to specifically identify sites on which the product may be applied in the directions for use: "Ornamentals: Christmas tree plantings, conifer seed orchards, and rhododendrons." In this example, the product user is restricted to using the product only on those three use sites. However, if a use site were indicated as "Non-cropland industrial sites, *such as*, airports, fence rows, roadsides, and associated rights-of-ways", then the user could use the product on any place that would fall under the category as non-cropland industrial sites. Reviewers should not accept an open-ended site list, including those extended by "such as" or lists ending with "etc.", where food uses may be involved.

D. Site-Pest Considerations

Site-pest combinations must be appropriate. Pests for which control is claimed must occur as pests at the sites with which the label associates them. Claims for control of a pest on or at an inappropriate site could mislead the user and possibly result in a misapplication of the pesticide. Examples of inappropriate pest/site claims include: control of algae in toilet bowls and brown dog ticks in commercial kitchens. If such inappropriate site-pest combinations are detected during label review the registrant must be advised that such claims are unacceptable.

E. Sites and the Intended User

The listed sites should be appropriate for the intended end-user. For example, sites listed on the labels of residential use products should be typical household/garden sites and not commercial agricultural sites such as cotton, tobacco, or cranberries.

VIII. The pests being claimed

The term pest is defined by statue and by regulation in *FIFRA 2(t)* and *40 CFR 152.5*. The label must clearly state the pest(s) (associated with a site) that are controlled by the product (*FIFRA 2(ee)*). Pest claims may be made in the Use Restrictions section or with specific application instructions. In addition, pest claims often may appear on the front panel as part of the name of the product or in promotional statements appearing under the product's name or elsewhere on the label.

A. Consistency of Listed Pests

Wherever the pests are listed on the label, they must be consistent with pests listed elsewhere on the label. For example, if the front panel lists fire ants as a target pest, then the directions for use must include the appropriate treatment directions for fire ants. If the front panel lists several pests and then references other pests controlled by using phrases like "and more", or "plus others" or "and many more", these phrases will only be acceptable if they are followed by a direct reference to the Directions for Use section for the complete listing

of pests controlled, i.e., "and more listed on the back panel". The reviewer must make sure that the directions for use are actually included and are applicable to all pests listed anywhere else on the labeling. This consistency is necessary to ensure that the product is not considered misbranded.

B. Pest Groupings

While target pests may be named very generally in the directions for use section of some labels (e.g., ants), other labels may identify them specifically, (e.g., carpenter ants). In the case of public health antimicrobial products, however, each strain of a pest listed on the label must be supported by appropriate efficacy data so that both the common and generic terms may be used if appropriate. The directions for use should be determined by and reflect the strain, location and behavior of the pest as closely as possible.

C. Product Formulation and Pests

When evaluating the target pests it is important to keep in mind the relationships among pests, application methods, and product formulations. For example, a liquid formulation of a pesticide such as parathion restricted to foliar aerial application would be unlikely to control soil-inhabiting insects such as corn rootworm larvae. If the reviewer is unsure whether a formulation could be expected to control a certain pest on a label, the reviewer must consult with the appropriate efficacy reviewer(s). The applicant must be informed if the proposed use is not found to be acceptable. The applicant may appeal such a decision. Typically, the applicant would then be required to supply information (such as product performance data) to the Agency indicating that its formulation is appropriate for the proposed use.

D. Pests and Use Sites

The pests listed on the label should be appropriate for the intended use sites for the product. For example, pests listed on the labels of residential/household use products should be typical household/garden pests. An agricultural crop specific pest such as the cotton bollworm would not be an appropriate pest claim for the label of a product intended only for use around the home.

IX. How the product is prepared and handled

Complete information on how to prepare, handle and apply the pesticide product must appear on the label. In order to satisfy the unreasonable adverse effects standard of FIFRA, label reviewers will, on occasion, need to disapprove of or modify label language submitted in the application for registration. Such modification may take the form of specific prohibitions ("Do not apply this product by use of aircraft") or general statements limiting use to methods indicated on the label ("Apply this product only by the methods listed and described on this label").

A. Formulation Type

Information regarding the product's formulation is essential for the proper preparation, handling and application of a product. For example, the label must clearly identify the formulation type of the product (dry, liquid, bait, or a gas, such as certain fumigants). The label must also specify if the formulation is "ready-to-use" or a concentrate which requires dilution and/or mixing. Aerosols, dusts, baits, granulars, and some liquids are examples of ready-to-use formulations.

B. Mixing Instructions

Some products must be mixed or diluted with other materials prior to application for pest control purposes. Labels for liquid formulation identified as concentrates, and dry products identified as "wettable powders", *must* have directions for mixing or diluting. Mixing directions must be as clear as possible and presented in easily measurable units (e.g., *not* "add 2.678 ounces to a gallon"). The units of measurement must be units by weight for dry formulations (pounds, ounces), and units by volume for liquids (pints, quarts, fluid ounces) or their standard abbreviations. One of the most frequent labeling errors observed is the use of "oz." for liquids instead of "fl. oz." Metric units may be used in parentheses after the correct English units. The diluent must be specified, even if it is water.

Dilution instructions may be presented in the form of a chart or table. Basically, the dilution directions should state mix "X" amount of pesticide with "Y" amount of water (or other diluents such as oil) to achieve a particular dilution, such as a 1% emulsion.

While the label may include a general statement such as "Use sufficient water to obtain full coverage of foliage", the label also should give specific directions for the use site to indicate the appropriate amount of spray volume to apply per unit area for aircraft or for ground equipment. It also may be necessary for the label to indicate the diluent spray volume amounts for aircraft or ground equipment.

1. **Tank Mixing Statement.** When the label bears a reference to mixing with other products, the Agency recommends that the registrant add a statement such as the following:

   "Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures".

C. **Compatibility with Other Products.**

EPA will not accept or require a label prohibition against the use of one pesticide product with another product unless that statement is necessary to protect human health or the environment, or to prevent illegal pesticide residues under Federal Food, Drug and Cosmetic Act (FFDCA). For example, a label statement prohibiting the mixing of products, if mixing would cause an explosive chemical reaction, would be acceptable. When compatibility with other pesticides or liquid fertilizers is being addressed, the label should include specific instructions or recommend a jar test.

X. Application information

What goes in this subsection will vary considerably according to the type of pesticide product and the intended user. However, this subset of the Directions for Use section should indicate use precautions and restrictions that apply to *all* sites and pests claimed on the label. For products with many registered uses, it may be useful and efficient to provide separate directions which pertain to specific sites and pest combinations claimed for the product. In such cases, each site and pest would have its own subsection which would be further divided into subsections such as "USE RESTRICTIONS" and the other elements specific to that grouping.

Some requirements specific to how the products is to be applied might be more efficiently placed under subsections pertaining to applications rather than under "USE RESTRICTIONS". The Use Restrictions subsection generally indicates the following:

- the pests for which control is claimed;
- the sites where the product may be used;
- any FIFRA 2(ee) limitations statements;
- other use limitations and requirements such as those statements pertaining to Chemigation, Spray Drift Labeling, seasonal restrictions, weather or time-of-day restrictions, requirements intended to protect nontarget species or contaminations of food or feed crops, and other basic requirements pertinent to safe and effective use of the product.

A. **Timing**

The label should clearly specify when the product should be applied to maximize the effectiveness of the product while complying with any regulatory requirements. If appropriate, the season, and/or the stage of growth of the plant when the pesticide is to be applied should be specified. Other timing/application descriptions include preplanting, at planting, post harvest, dormant, or delayed dormant. If one of these timings is present, it should be so stated in a Special Directions column. The label's information concerning the timing of applications needs to be consistent with any regulatory intervals specified in

OPP's regulatory documents to mitigate risk from residues of the active ingredient (or product).

1. **Regulatory Intervals to Mitigate Risk.** The label reviewer should check the residue chemistry assessment and RED to determine if any regulatory intervals were recommended for the product's label. The residue chemistry assessment for a given product or active ingredient may specify the following intervals:

   - Pre-harvest Interval (PHI)
   - Pre-slaughter Intervals
   - Pre-grazing Intervals
   - Pre-feeding Intervals
   - Pre-silage Intervals

   If required to meet the FIFRA standard, the PHI should be indicated as numbers of weeks or days. Preslaughter intervals and pregrazing intervals should be expressed similar to the PHIs.

2. Regulatory Interval for Antimicrobials. The key timing factor for antimicrobial disinfectants or sanitizers is the length of time the product must be in contact with the surface being treated in order for the treatment to be effective. This information should be clearly stated on the label. The final disinfectant test guidelines for use of antimicrobials on hard surfaces (OCSPP 810.2200) issued in 2012 specify that disinfection of hard surfaces be achieved within a disinfectant product contact time of 10 minutes or less.

B. Application Methods

1. **Methods and Types of Equipment.** When necessary the label must indicate the types of equipment that may be used in applying the pesticide. The type of equipment should be identified in a level of detail sufficient to promote safe and effective use of the product. For example, ground and aircraft sprayers should be described by type and performance requirements (output and safety specifications) to the extent that such descriptions are needed. The same concept applies to spreaders, injectors, burrow builders, and any other specialized equipment. Specific brands and models of equipment should not be indicated unless specific information is provided to indicate that only that brand and model are appropriate for reasons of safety or efficacy. Some types of equipment are designed specially to apply particular types of pesticide or to interface with particular containers in which certain especially hazardous products are packaged. Use directions should prohibit use of types of equipment known to be inappropriate for handling the product or any of the mixtures that the label directs users to prepare. When

the method of application and necessary equipment are specific to each site and pest combination, they should be indicated in the directions that pertain to each combination.

The label reviewer should make sure that the methods of application and equipment recommended are appropriate for the product formulation, the intended user, and the site and pest to which the pesticide product is being applied. Complete information on how to apply the product should be included. For example, the statement "Apply this product to the soil" is not sufficient. Labels which state that the pesticide must be applied to the soil and immediately incorporated must specify what kind of equipment must be used.

2. **Liquid Spray Instructions.** Labels for liquid formulations generally refer to "spraying" the product as the method of application. Labels that have directions which instruct users to mix a spray solution should provide special instructions devoted to preparing spray mixes and should indicate the spray volume to be applied per acre or per unit area. For some applications it may be acceptable for the label to indicate, "apply sufficient volume for thorough coverage" or similar language. The following types of spray applications are generally used:

   (a) *Space Spray*. Dispersal of the product into the air by foggers, misters, aerosol devices or vapor dispensers for control of flying pests and exposed crawling pests.

   (b) *General Area Spray*. Application to broad surfaces, such as walls, floors and ceilings.

   (c) *Spot Spray*. Application to small areas on which pests are likely to occur. These areas may be on floors, walls, bases or undersides of equipment. To limit potential exposure in a commercial food area, a "spot" should not exceed two square feet.

   (d) *Crack and Crevice*. Application of small amounts of pesticide into cracks and/or crevices in which pests hide or through which they may enter a building. Such openings commonly occur at expansion joints, between elements of construction and between equipment and floors.

   If a label being reviewed uses any of the application terms mentioned above, determine if the terms are appropriate, considering the use patterns on the label.

3. **Dust Formulations.** For dust applications, a statement such as "apply uniformly for thorough coverage of plant surfaces" may adequately substitute for a specific application rate. However, a maximum application rate must be specified in order to avoid over-exposure.

4. **Aerial Applications.** For aerial applications, spray volumes should be stated.

5. **Spreader Settings.** Spreader settings may vary from product to product. Such changes in spreader settings are not usually considered significant.

6. **Total Release Foggers.** If the product label being reviewed is a total release fogger that contains a highly flammable ingredient, the following label text must be included in the Directions for Use *40 CFR 156.10(i)(2)(x)(D)*, preferably with this statement from *PR Notice 98-6*:

   "DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. DO NOT use in a room 5 ft. x 5 ft. or smaller. Instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames or running electrical appliances that cycle off and on (e.g., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights".

C. **Application Rate**

1. **Agricultural Products.** The actual application rate, (e.g., *how much product* to apply per unit area or per placement) must be stated in the Directions for Use. Labels for agricultural products usually express the application rate in terms of pints/acre for liquid formulations, or pounds/acre for solid formulation. The Directions for Use for an agricultural pesticide used in a spray solution also must indicate the spray volume/unit area or other measurement of coverage, depending on the type of formulation.

2. **Residential Use.** Labels for residential use products should express the application rate in smaller units, such as ounces, teaspoons/gallon, or pounds/square foot. Such rates and units of measure are more appropriate for the home garden or yard. Any pesticide application equipment required by a residential user should be readily available, like simple equipment such as drop-spreaders or hose-end sprayers. The public generally does not have access to (and does not use) specialized equipment. When percentages are included in application rates, it should be clear whether percentages are by weight or volume and whether the percentage refers to the product or active ingredient. Percentage application rates should never be used alone. The specific amount of product to use per unit area should always be clearly stated in the Directions for Use.

3. **Net Contents and Application Rate.** The directions for use should not call for use of *more than* the net contents of the product's container (i.e., if a granular product is packaged as a 1 lb. unit, its application rate should not require 200 lbs. of product). If the product is a liquid, the specified treatment rate should be fl. oz. or gal. per unit area. If a solid, the rate should be expressed oz. or lb. per unit area. Note: Many labels of liquid formulations incorrectly omit the "fluid" (fl.) with the oz. when specifying application rate.

4. **Minimum Application Rate.** For certain justified reasons, minimum application rates are acceptable on product labels in certain situations. However, if one of the reasons below (a. or b.) cannot be documented, the minimum application rate should be stated in

advisory language. Enforceable (mandatory) minimum application rates are only warranted for the following reasons:

(a) When there is a risk that reduced application of the product may result in increased pest resistance to the active ingredient; or

(b) When there is documentation that a product's efficacy is substantially compromised under a certain application rate.

D. Frequency of Applications

The label should clearly specify how often the product should be applied to maximize the effectiveness of the product while complying with any regulatory requirements.

E. Other Information Pertaining To Specific Applications

Other information may include: method of application, equipment, application frequency (within the requirements for tolerance, appropriate for controlling pests, etc.), minimum volume of diluent for spraying for each type of equipment, application intervals, maximum amount of product or pounds a.i. per acre per application, or per season or year, phytotoxicity effects or warnings, number of applications per season and grazing or feeding restrictions. In cases where a maximum limit of a.i./crop, season, etc., is required, ensure that liquid products include a statement of weight/volume of either product or active ingredient.

XI. Additional application information

This subsection of the Directions for Use may be given any of several headings, including "*Application Instructions*", "*How to Apply*" (especially for household/residential-use), and "*Baiting*" as appropriate. In cases for which there is only one site/pest category but several application methods, it may be appropriate to have separate application subsections for each method (e.g., "Area-wide Spraying"; "Spot Treatment", etc.).

This Directions for Use subsection contains the specific instructions and information needed to apply the product on each relevant crop/site for each target pest. Directions may be grouped according to the sites and pests to be treated (e.g., broccoli, cabbage, cauliflower: cutworms, fall armyworms, cabbage loopers). If geographical restrictions are required, individual States or counties should be listed; geographical regions (e.g., the Northwest) are unacceptable because they are not specific enough to be enforceable.

Unique, detailed sets of application directions will be required for certain pests (e.g., fire ants, pocket gopher). Furthermore, fungicide grouping may be used ONLY if *all* pests occur and are controlled on *all* of the crops in the group. Plant diseases are commonly specific to a site, (e.g., Black Spot on roses). Any geographic restrictions need to be included with their appropriate sites/crops.

XII. Storage and disposal instructions

Labels for pesticide products are required to bear labeling instructions for the storage and disposal of pesticides and pesticide containers in the Directions for Use section of the label . It is preferred that the Storage and Disposal instructions appear at the end of the Directions for Use section. Information about and requirements for Storage and Disposal instructions are given in *Chapter 13*.

Appendix A—Directions for Use Checklist

Standard Elements
1. Does the label have: The correct heading "Directions for Use"? The required Misuse Statement? If the product has additional misuse statements are they acceptable? Appropriate Storage and Disposal information?
Appropriate labeling required in RED(s) or latest risk assessment document?

Technical Elements	
Elements to Consider	
2.	Is the product subject to the guidance set out in PR Notice 87-1 (chemigation)? If so, is there adequate chemigation information or a chemigation prohibition statement?
3.	Is the product subject to the Worker Protection Standard (WPS)? If so, does the proposed label contain all the required, accurate WPS information as set forth in the regulations and the guidance in Chapter 10 Is the Re-entry Interval in the Agricultural Use Requirements box correct?
4.	Are the following elements (*if applicable*) adequately expressed: Instructions and Information Subheading? Use Restrictions? Spray Drift Language? Endangered Species Statement? Pollinator Protection Statement?
Sites and Pests	
5.	Are the sites and pests identified?
6.	Are there appropriate tolerances or exemptions from tolerance for all of the ingredients in the product to cover all the food use sites listed?
7.	If peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, Crustacean, or wheat commodities are listed on the confidential statement of formula, do the use sites and application methods comply with 40 CFR 180.1071?
8.	Is the formulation acceptable for this site/pest combination?
9.	If a RED has been issued, is the site eligible for Reregistration?
10	If the product contains more than one active ingredient, are all the uses acceptable for all the active ingredients (AI)?
Application Instructions	
11.	Are adequate preparation and handling instructions included?
12.	Are the application rates indicated?
13.	Are the rates appropriate and calculated correctly?
14.	Does the product density (eg. lbs of AI/gallon) times the application rate agree with the tables that list the weight of AI applied to a given area?
15.	Do the rates deviate from a standard use pattern?
16.	Is the rate of application consistent with the packaging of the product?

Application Instructions	
17.	Is the application frequency acceptable?
18.	Is all equipment (e.g. for mixing, loading or application) identified/specified and is the equipment practical for the user?
19.	Are all methods of application appropriate?
20.	Is the timing of the applications appropriate?
Use Restrictions	
21.	Should there be a Use Restrictions sub-heading and section?
22.	Is the Pre-harvest Interval, Pre-grazing, Pre-feeding, Pre-silage or Pre-slaughter Interval correct?
23.	Are site specific precautions and restrictions clearly listed with each site/pest combination?

Overall Quality and Consistency	
24.	Is the Directions for Use heading prominent enough (e.g., bold, larger font, underlined, etc.) so that it is clear to the user that everything that follows falls under the Directions for Use section?
25.	Does the label contain complete Directions for Use? Or are the detailed directions for use omitted because the product is an MUP or for veterinary use or for use in non-pesticide manufacturing?
26.	Are the Directions for Use clearly written with no contradictory or ambiguous language?
27.	Are terms with clear definitions used?
28.	Is the label free of false and misleading claims?
29.	Are label statements worded appropriately as mandatory or advisory?
30.	Is the label organized in such a fashion that it is clear what is mandatory, and what is advisory?
31.	Are terms such as "recommended" and "avoid" absent from all mandatory directions? (Ensure the phrase "recommended use rates" is not stated on the label.)
32.	Are the Directions for Use presented in the most effective, clearly understood and efficient way possible? Could the label benefit from the use of chart or graphs?
33.	Are there questions on enforceability? If so, has OECA been consulted?
34.	Are Precautions and Restrictions clearly presented?
35.	Does the label comply with all applicable Pesticide Registration (PR) Notices? See http://www2.epa.gov/pesticide-registration/pesticide-registration-notices-year

Check *40 CFR 156.10* for further guidance.

Revised November 2013

Label Review Manual

Chapter 12: Labeling Claims

National Garden Bureau

I. Introduction

This chapter provides guidance for reviewing claims made on proposed labels. A label claim is a statement of something as a fact or an assertion on the label open to challenge. For purposes of this chapter there are three types of claims: 1) general claims, 2) claims associated with the product name, and 3) efficacy related claims. This chapter also provides guidance on Warranty and Disclaimer statements on labels and claims made in advertising.

II. General claims

Every pesticide must have labeling which is accepted by EPA before the pesticide can be sold or distributed. Labeling is defined in the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(p)(2)* as meaning labels and all other written, printed, or graphic material accompanying a pesticide or device at any time or to which reference is made on the label or in accompanying literature. As defined in *FIFRA Section 2(q)(1)(A)* a pesticide is misbranded if its labeling bears any statement, design or graphic representation which is false or misleading. *FIFRA Section 12(a)(1)(E)* provides that it is unlawful for any person to distribute or sell any pesticide which is misbranded. EPA's regulation, at *40 CFR 156.10(a)(5)* provides examples of statements that are considered to be misbranded; such as:

- A false or misleading statement concerning the composition of the product;
- A false or misleading statement concerning the effectiveness of the product as a pesticide or device (EPA may review and approve or disapprove non-pesticidal claims appearing on a pesticide label);
- A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- A false or misleading comparison with other pesticides or devices;
- Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by an agency of the Federal Government;
- The name of a product if the name suggests some but not all the active ingredients in the product, even though the names of the other ingredients are stated elsewhere in the labeling;
- A true statement used in such a way to give a false or misleading impression to the purchaser;
- Label disclaimers or warranty statements which negate or detract from labeling statements required under FIFRA and EPA's regulations;

- Safety claims of the pesticide, or its ingredients, including statements such as trusted, safe, nonpoisonous, noninjurious, harmless or nontoxic to humans and pets with or without such a qualifying phrase as when used as directed.

- Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
  - "Contains all natural ingredients"
  - "Among the least toxic chemicals known"
  - "Pollution approved"

For certain aquatic use products, claims to reduce sludge and unpleasant odors in water or to clean, clarify or deodorize ponds and lakes are not considered pesticidal claims; nor are claims regarding the reduction of nutrients and organic matter in water, provided no claim is directly made or implied that the reductions will result in reduced pest populations. The claims "Reduces critical nutrients for cleaner, clearer ponds", "Ponds with algae need to reduce nutrients", and "Bacterial Product to Control Excess Nutrients for Clear, Clean Ponds" imply pesticidal use and therefore require registration.

Slime and odor control agents and other products expressly claiming control of microorganisms of economic or aesthetic significance are **not** considered to be public health related, but should bear accurate pesticide labeling claims. Registrants are still responsible for ensuring that these products perform as intended by developing efficacy data, which must be kept on file by the registrant.

EPA's policy does *not* permit the use of the terms "natural", or "naturally" in the labeling of any registered product, including biopesticide products, both microbials and biochemicals. These terms cannot be well defined, and may possibly be misconstrued by consumers as a safety claim.

The claim "new" may be used on the labeling of a product of new composition for a period of 6months following approval of the labeling; however, the word "new" may not be a part of the product name of record. Ifa label reviewer is in doubt as to whether a claim or statement is false or misleading, he or she should consult their division's Ombudsperson or OGC representative before allowing the claim. *PR Notices 98-10* and *93-6* also provide guidance on claims, however, the statute and applicable regulations take precedence.

III. Some examples of unacceptable claims

- Statements that imply or suggest that the product can or will prevent or control disease or offer health protection, such as an insecticide that claims control of Lyme disease.

- "Commercial Line," "Commercial Size", "Institutional Size", "Garden Center Size": The use of these terms for products clearly intended for consumer household use is misleading.

- "Kills Numerous Insects", "Kills Many Insects", "Kills All Insects": These claims imply a greater range of effectiveness than labeled. If however, these claims are limited to those pests listed on the label, i.e., "Kills many insects as listed below (or as listed on the label)", it may be acceptable.

- Claims about the *Absence* of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by *40 CFR 156.10 (a)(5)*. These claims are examples of a true statement used in such a way as to give a false or misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained or was not likely to contain in the first place.

- "Child Resistant Package" or Other CRP Related Claims: If a pesticide product requires child-resistant packaging (CRP), and has complied with the CRP regulations in *40 CFR 157* then the claim to that effect on the label is acceptable. Whether CRP is mandatory or voluntary the label may indicate the use of CRP and the proper use instructions for the CRP. However, in no circumstances may any safety claims beyond the statement "in Child Resistant Packaging" be made due to the use of CRP.

- "Organic", "For Organic Lawns", "Organic Disease Control", "An Organic Alternative to _____", and "Your Organic Solution" are all examples of misleading label claims as to safety. Under the National Organic Program (NOP), the phrase, "*For Organic Production*", and "*For Organic Gardening*" located on the front panel of the label in close proximity to the product name are examples of acceptable labeling statements relating to the term "organic". The phrase should not appear above the product name (in the location normally reserved for a Restricted Use Statement). See the next section for more information on organic claims.

- Biodegradable: The term "biodegradable" is generally unacceptable for any pesticide product. Except the term may be used only in reference to the package or packaging and then only if the registrant certifies that the package breaks down and they provide information to support it. Otherwise "biodegradable" may not be used on a pesticide label in any context.

- Claims Such as "Prevents Infection", "Controls Infection", or "Prevents Cross Infection" or that the product will control or mitigate any disease, infection or pathological conditions constitute public health claims and are not acceptable.

- The term "steri-" implies sterilant activity and is not acceptable as a product name or on a product label unless it is a sterilant.
- Statements that imply indefinite or all encompassing protection against bacteria, fungi or algae such as "germ-free", or "algae-free" are not acceptable.

IV. Pesticides Eligible for USDA's National Organic Program

Certain information on the pesticide label assists organic growers in knowing which products meet the requirements of the National Organic Program (NOP) Rule. If the criteria described in *Pesticide Registration (PR) Notice 2003-1*, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1-clarification.html are met, a pesticide product may bear the following phrases

"For Organic Production",

"For Organic Gardening",

"For Organic Lawn Care", and

"For Use in Organic Production".

Label language and/or logos from other groups that review materials proposed for organic agriculture may also be considered (E.g. OMRI). The reviewer needs to determine if this information is false or misleading. Label reviewers should consult with the National Organic Program Liaison in the Biopesticides and Pollution Prevention Division for an evaluation of the product's proposed labeling before approving any organic claims, regardless of whether BPPD is the registering division.

V. Claims made about the active ingredient

A product label may include the statement "contains [name of active ingredient], the active ingredient used in [Brand Name (™ or ®)]", if the following criteria are met:

A. Placement

The claim may be placed anywhere on the label, however the preferred location is in close proximity to the Ingredient Statement.

B. Presentation

The claim should not be presented in an overly large font, such that the claim is set in a font type no larger than that of the Signal Word on the label. Furthermore, the claim should not be presented with heavily bolded or highlighted type or use coloring to cause the claim to

excessively stand out over the rest of the labeling text. The format of the claim should not be in such a way that is causes greater attention than other required precautionary labeling on the label.

C. Appropriate Comparison

If the subject product is a single active ingredient product, the claim should only refer to another similar single ingredient product. If the subject product is a multiple active ingredient product, the claim should only refer to another similar multi-ingredient product with the same active ingredients. Appropriate disclaimers stating that the generic product is not manufactured or distributed by the maker or marketer of the brand-name product as well as the trademark of the brand may be cross-referenced by use of a footnote.

VI. Product names

The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label. See *40 CFR 156.10(b)*. No name, brand, or trademark may appear on the label which is false or misleading, or has not been approved by the Administrator through registration, or that the Agency has been notified of a name via supplemental registration, as an additional name pursuant to *40 CFR 152.132*, or by notification as allowed by *PR Notice 98-10*.

Product names cannot constitute false and misleading claims. Although a company has the discretion to name its product, the company is still governed by the false and misleading standard. An example of a misleading product name is, "*Fresh Squeezed Disinfectant*". The phrase "Fresh Squeezed" in the name is misleading because it could convey that the product is meant to be consumed. Following is the Agency's current guidance on false or misleading product names:

1. Product names, claims or statements that express or imply a higher-level of efficacy than demonstrated by testing are not acceptable.

2. General superlative terms such as "super", "superior", and "ultra" no longer need to be qualified by the term "brand" in a product name. However, this determination still does not allow terms or claims like those which clearly imply heightened efficacy (e.g., "hospital strength", "professional strength", etc.) (see PR Notice 93-6).

3. The Office of Pesticide Programs is under no obligation to ensure registrants use the correct trademark ™ or ® and copyright © symbols on labels. Registrants are encouraged to use the correct symbols.

4. If a product falls within the scope of the Worker Protection Standard and contains an organophosphate (i.e., an N-organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the

label shall indicate the term directly under the Product Name or in the first aid statement. *40 CFR 156.206(c)(1)*.

The exact same name cannot be used for different products registered by any registrant. *40 CFR 156.10(b)(2)(ii)*. The product name must be sufficiently different to clearly distinguish one product from another. However, a supplemental distributor may use the same product name as the parent product. See *40 CFR 152.132(d)*.

VII. Efficacy-related claims

Even though registrants/applicants must conduct efficacy studies, the Agency only routinely requires the submission of these studies for certain types of products. Nevertheless, each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration. EPA routinely reviews efficacy data (also referred to as product performance data) when a pesticide product bears a claim to control pest organisms that pose a threat to human health. Such pests include, but are not limited to, (a) microorganisms which are infectious to man in any area of the inanimate environment, (b) vertebrates (e.g., rodents, birds, bats, dogs, and skunks) that may directly or indirectly transmit diseases to or injure humans, and (c) insects that carry human diseases (e.g., mosquitoes, ticks, etc.). *40 CFR 158.400*. EPA also requires submission of efficacy data to support claims for the control of termites. On a case-by-case basis, the Agency may require substantiation of an efficacy claim.The following points should be kept in mind when reviewing labels bearing public health efficacy claims:

1. The terms "microbiocide", "microbicide", and "microbiostat" generally are not acceptable on a public health product. If used on a non-public-health product, the claim must be qualified to indicate that the product does not provide public health protection.

2. The term "biocide" generally is unacceptable on a public health product because it implies that the product can kill all living organisms. It may be used on a non-public-health product provided it is qualified by directions for use or other statements that make clear the types of organisms to be controlled.

3. True, non-misleading claims regarding the effectiveness of a product against target pests, e.g., "kills roaches", "controls target pests", and "kills pests on contact" are acceptable. However, such claims may not be exaggerated or used in a way that would make them misleading. EPA may require additional efficacy data to substantiate claims that go beyond mere control of claimed pests. *PR Notice 93-6*.

4. Terms which describe a specific level of efficacy and which are standard EPA-accepted claims such as "bacteriostatic", "sanitizer", "disinfectant" and "sterilant" are acceptable when data supports their use. *PR Notice 93-6*.

5. Implied claims (e.g., any statement, design, graphic representation or brand name) of heightened efficacy of a pesticide product by itself or as compared with another product or device are false and misleading. Examples of such claims include, but are not limited to: "professional strength", "extermination strength," "hospital strength", "industrial strength", "institutional strength", "super strength", "ultra strength", "maximum strength", "maximum efficacy", "extra strength", "double-strength", "triple-strength", "hospital grade", "high potency", and "high-powered" *PR Notice 93-6*.

6. Terms which function only to define a use site and which are not themselves claims of heightened efficacy, provided that such terms are not used in a manner that is misleading, are acceptable. For example, "hospital use" may be acceptable as long as it doesn't imply "hospital strength", is not used in the product name and is not highlighted on the label to the exclusion of other acceptable use sites. *PR Notice 93-6*.

7. Words or phrases that imply a product possesses unique characteristics because of its composition are not acceptable. See *40 CFR 156.10(a)(5)(i)*. Examples of such terminology are, "unique formula", or "strongest on the market". Other statements not supported by efficacy data that has been reviewed and accepted by the Agency are not allowed.

8. Claims that are inconsistent with efficacy established by testing are unacceptable. For example, a claim of 30-second efficacy is not acceptable if testing and/or use directions require two-minute contact time for efficacy.

9. Claims of efficacy based on an unsubstantiated, or improbable site/pest relationship are unacceptable. For example, a claim for control of Legionnaire's disease in cooling tower water is unacceptable.

VIII. Instructions to label reviewers for efficacy issues

Check with the efficacy reviewers if the label makes unusual claims, deviates from a standard use pattern, or if the formulation changes. For example, formulation changes in an antimicrobial product can alter the efficacy of the product. Also, alternate formulations are not acceptable for rodenticides. Request a formal efficacy review for all claims that differ significantly from existing claims.

As mentioned earlier, do not allow any claim that would render the product misbranded under FIFRA or false and misleading under *40 CFR part 156.10(a)(5)*.

IX. Warranty and disclaimer statements

Most, if not all, pesticide labels contain some type of warranty disclaimer language. It is important, as always, that the Agency be consistent in reviewing such language when it is first submitted or subsequently amended. Warranty and Disclaimer statements containing language intended to limit liability of the registrant or act as disclaimers or warranties for the product are generally covered by state law or may fall under the jurisdiction of the Federal Trade Commission. The Agency will evaluate these statements to assess the extent to which the statements impact FIFRA label standards or the Agency's implementing regulations. An EPA guidance document on warranty statements was developed in 2006 and the examples it offers may be consulted at this site: *http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf* . Also see Chapter 3, Section IV. C. (page 8) for information on what is allowable for warranty statements on distributor product labels.

There are four types of label language associated with disclaimers, warranties and limitations of liability that the Agency has found to be unacceptable under statutory and regulatory standards. It is important to recognize that these statements must be assessed on a case-by-case basis. They are as follows:

1. Overly broad statements negating or detracting from the Directions for Use or other label language (including precautionary statements and directions for use). For instance, a warranty statement that the product may not work would undermine Directions for Use that explain how the product is to be used.

2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights. (e.g., manufacturer states buyer's rights are extremely limited; "all of these conditions are beyond the control of registrant X"). Because these statements are almost always incomplete (in terms of fully explaining a buyer's rights in the jurisdiction (state) of purchaser and because they can mislead buyers into thinking that they have no legal remedy, they may constitute "misbranding" under FIFRA.

3. Overly broad language implying buyer has no legal right to recover damages from manufacturer (e.g., "all such risks shall be assumed by the buyer").

4. Because EUP labels must be used in strict accordance with the EUP program, the warranty on EUP labels may not disclaim control over use. As with No. 2 above, these statements can be considered to be misleading.

The reviewer should check the proposed label for warranty/disclaimer/liability language statements (like those above) that appear to negate or detract from Directions for Use or other language. The label reviewer should make sure that the disclaimer statement makes it clear that it is the **registrant's** or **manufacturer's** warranty disclaimer, by using such statements like "To the fullest extent permitted by law, the manufacturer shall not be liable..." or "It is the manufacturer's intention that...". This way it is clear that the language is coming from the registrant (and not EPA).

The following are examples of problematic warranty statements. The problematic portions of the label statements are stricken, and necessary language is added in red.

EXAMPLE 1

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and ~~should~~ must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of XXXX. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, XXX makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of XXX is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, XXX disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at XXX's election, the replacement of product.

Reasons for Corrections

The phrase "should follow directions" could mislead users to believe that the directions for use are only suggestions and not enforceable restrictions on how the product may be used; therefore, all statements relating to using the product in accordance with its labeling will be required to be mandatory (i.e., "must").

The phrase, "to the extent consistent with applicable law" has been added to the disclaimers of liability and damages to avoid the statements being false or misleading. Some states or localities may not allow certain disclaimers of liability or damages; therefore, the user/buyer may have a remedy under other law governing warranties.

EXAMPLE 2

Warranty and Disclaimer Notice

Warranty

The directions for use of this product are believed to be adequate and ~~should~~ must be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result due to such factors as weather conditions, presence or absence of other materials, or the manner of use or application, all of which are beyond the control of XXX, the manufacturer, or the seller.

To the extent consistent with applicable law, the products sold to you are furnished "as is" by XXX. The manufacturer and the seller are subject only to the manufacturer's warranties, if any, which appear on the label of the product sold to you. Except as warranted by this label ~~expressly provided herein~~, XXX, the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. ~~Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product~~. To the extent consistent with applicable law, Buyer's or user's exclusive remedy, and XXX, the manufacturer's or the seller's total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of XXX, or the seller is authorized to amend the terms of this warranty disclaimer or the product's label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, XXX, the manufacturer, or the seller shall not be liable for consequential, special, or indirect damages resulting from the use,

handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

Reasons for Corrections

Prior to legal use of a pesticide product it must be registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). Registration of a pesticide requires, in part, that the product be effective in controlling the pest(s) for which it is registered. In registering the product under FIFRA, the product must perform as purported when used in accordance with its labeling. The phrase, "Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product", is overly broad and could be misleading to the consumer. Overly broad statements, which negate or detract from the Directions for Use, must be qualified by a phrase such as "Except as warranted in this label". Statements such as those used in the example above ("Except as expressly provided herein" and "Except as expressly stated herein") are not adequate qualifiers because they are misleading in that they do not clearly incorporate the warranty offered through the act of registration.

State and local laws may not allow the manufacturer to limit its liability by offering its product "as is". In addition, the same laws may not allow certain limitations of liability or remedy. Therefore "to the extent consistent with applicable law" has been added in appropriate places.

More examples of Warranty and Disclaimer Statements can be found on EPA's *Labeling Committee Projects* Web site. If, after reviewing the examples, a label reviewer is still in doubt as to the acceptability of any warranty or disclaimer statement, the statement should be referred to the Office of General Counsel.

X. Claims made in advertising

Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. See *FIFRA § 12(a)(1)(B)*. In other words, if a claim is not on the label or substantially differs from what appears on the label (or any part of its distribution or sale which for example appears on a brochure), it cannot be made in advertising. Although OPP does not routinely review advertising in connection with the registration, the Agency may require advertising used in the marketing of the product to be submitted upon request and be reviewed to see that it is in compliance with *FIFRA section 12(a)(1)(B)*. If reviewers come across any advertising inconsistencies, refer them to the following address for further investigation:

Branch Chief
Agriculture Branch
Agriculture Division
Office of Compliance (2225A)

Revised July 2013

Label Review Manual

Chapter 13: Storage and Disposal

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Elizabeth A. Sellers

I. Introduction

This chapter discusses the storage and disposal instructions for pesticides and pesticide containers. Label reviewers should use this chapter as well as information presented in PR Notices *83-3*, *84-1*, *84-5*, *94-2*, *2007-1*, and *2007-4*; in the regulations at *40 CFR §156.10(i)(2)(ix)* and *§§156.140–156.159*; and in *Reregistration Eligibility Decision (RED)* documents or *Registration Review Decisions* for active ingredients. In addition, chemical-specific storage and disposal statements have been provided by the Agency for certain pesticides, as stated in *PR Notice 84-1* (and an errata sheet dated April 12, 1984), and in PR Notice *84-5*. These chemical-specific statements are described in detail in this chapter.

According to *40 CFR §156.10(i)(2)(ix)*, pesticide products must have label instructions for the storage, residue removal and disposal of pesticides and pesticide containers. For many years, the content of these Storage and Disposal instructions has been established in PR Notices. The labels of pesticide products "released for shipment"[1] after August 16, 2011 must bear Storage and Disposal instructions that also conform with the requirements in Subpart H – Container Labeling, *40 CFR §§156.140 – 156.159*. However, registrants may submit to the appropriate EPA Product Manager team a request for a waiver or modification (with a justification) from EPA for any of the requirements in Subpart H. *[If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§*156.140 – *156.156 or if otherwise allowed by EPA.(See PR Notice 2007-4)*

This chapter is organized so that general information is provided in section II followed by instructions for a general storage and disposal state in section III; pesticide storage in section IV; pesticide disposal in section V; and container handling (i.e., container cleaning instructions, reuse limitations, and container recycling or disposal) in section VI. Next, section VII describes how to present information on one label for multiple uses, container types and/or sizes. Attachments follow with information on (A) pesticide storage statements for products with certain active ingredients; (B) storage statements suggested by EPA; (C) container handling instructions by container type; and (D) sample storage and disposal statements for antimicrobial pesticides.

II. Reviewing the statements

A. Determining Storage and Disposal Labeling

The Storage and Disposal section of the label **must have** instructions on how to:

- Store a product
- Dispose of leftover pesticides
- Clean an empty container (for certain types of pesticides and containers)
- Dispose of an empty container if recycling or reconditioning is not an option.

In addition, the Storage and Disposal section of a label **may have** instructions on how to:

- Dispose of pesticide rinsate
- Return the container for refilling (for sale or distribution), if it can be reused.

[1] The definition of "released for shipment" in *40 CFR* §152.3 is: "…A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment until subsequent activities, such as relabeling or repackaging, constitute production."

B. Statement Location

Storage and Disposal instructions *(except for batch codes)* must be ***grouped*** together under the heading "Storage and Disposal" and should be ***within*** the "Directions for Use" section ***at the end***, while clearly ***set apart*** (as blocked or in a box) from the rest of the "Directions for Use". *(See §156.10(i)(2)(ix) and PR Notice 83-3)*

EXCEPTION:

All but one of the container statements required by *40 CFR 156.140 – 156.159* can be placed on the actual container (not on the closure) itself. Specifically, the container type, container reuse and container recycling or reconditioning statements can be on the container, but not the cleaning instructions. Cleaning instructions must always be on the label itself. When statements are on a container the label must have an appropriate statement under "Storage and Disposal" that directs the user where to find the information. *Examples* are: "See container for recycling [*or other descriptive word*] information" or "Refilling limitations are on the container."

Any container statement required by *40 CFR 156.140 – 156.159* and put directly on the actual container itself must be durably marked such as by (but not limited to) etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink. *(See §156.140)*

C. Format

If it is a nonrefillable container and the container handling statements are placed on the label (or labeling), registrants must use an appropriate subheading under the heading "Storage and Disposal". *(See §156.140(a))* Alternatively, for refillable containers the Agency suggests (does not require) a subheading Subheadings commonly used are "Container Handling"or "Container Disposal". However, when making label revisions EPA recommends that registrants transition to using "Container Handling".

The example below shows the order and subheadings of a typical storage and disposal section of a label for a non-residential[2] use product.

DIRECTIONS FOR USE

Storage and Disposal
Do not contaminate water, food, or feed by storage or disposal.

Storage[3]:
[Where and how to store the product.]

Pesticide Disposal[4]:
[What to do with product that is left over and not going to be used.]

Container Handling[5]:
[Whether the container is nonrefillable or refillable; if it can be reused, recycled or reconditioned; how to dispose of it if recycling or reconditioning is not an option; and how to clean it if cleaning is required.]

[2] In this version of Chapter 13, EPA has simplified the phrase "residential/household use" from PR Notice 2007-1 for clarity, particularly when describing the opposite set of products. The phrase "non-residential use" is more clear than "non-residential/household use" or non-residential/non-household use". See footnote 10 for more details.

[3] Registrants may use alternative subheadings such as "Pesticide Storage" or "Product Storage", with the approval of the EPA reviewer and/or EPA Product Manager.

[4] Registrants may use alternative subheadings such as "Product Disposal" or "Disposal" with the approval of the EPA reviewer and/or EPA Product Manager.

[5] Registrant may use alternative subheadings such as "Container Disposal" with the approval of the EPA Reviewer and/or EPA Product Manager. When making label revisions, EPA recommends that registrants transition to "Container Handling."

D. Type Size Requirements

The heading "Storage and Disposal" must be in type of the same minimum sizes as required for the child hazard warning by 40 CFR 156.60(b). *(See §156.10(i)(2)(ix))*

III. General storage and disposal statements

The Agency historically has required all productsexcept for residential[6] use products to bear the following statement for risk management purposes:

"Do not contaminate water, food, or feed by storage or disposal".[7]

Preferably, registrants should place this statement immediately under the heading "Storage and Disposal" since it concerns both storage and disposal. However, it may be placed elsewhere within the Storage and Disposal section. *(See PR Notice 83-3)*

IV. Pesticide storage statements

Pesticide storage instructions are required by *§156.10(i)(2)(ix)*. Safe storage is essential to protect against accidental exposure to children, bystanders and workers, environmental contamination due to leaks and spills, and intentional exposure due to vandalism or terrorism. EPA has preferred storage instructions for certain active ingredients (section A); suggested statements for other products (section B); and guidelines for registrants developing their own storage instructions (section C). Registrants and EPA reviewers may use their discretion when choosing storage statements for any given product, unless certain instructions are specified in a PR Notice, RED, or a Registration Review Decision.

A. Preferred Storage Statements (for products with certain active ingredients)

As mentioned above, the Agency has preferred storage statements for products with the following active ingredients:

- Calcium hypochlorite - liquid and solid
- Chloropicrin
- Ethylene oxide
- Etridiazole
- Sodium hypochlorite - liquid
- Sulfuryl fluoride
- Methyl bromide and methyl bromide plus 2% or less chloropicrin
- Phosphide – aluminum and magnesium
- Sodium cyanide

For products with one of these active ingredients, see Attachment A for the appropriate storage statement(s). *(Note that a complete set of sample storage and disposal statements for liquid sodium and calcium hypochlorites as well as solid calcium hypochlorite can be found in Attachment D.)*

[6] "Residential" was previously referred to as "residential/household" in PR Notice 2001-6.

[7] EPA revised this statement to end "...by storage OR disposal" to correct an error in the 2008 version of Chapter 13 so it is consistent with PR Notice 83-3. When making label revisions, EPA recommends that registrants transition to the version of the statement that ends "...by store or disposal."

B. Suggested Storage Statements (for products with active ingredients not included in the list above)

A list of EPA-suggested storage statements for all other products (not listed above in A) is provided in Attachment B.

C. Developing Other Storage Statements

For products that do not have active ingredients listed above in section A, *PR Notices 84-1* or *84-5*, or that do not have storage statements provided by an Agency decision document (e.g., a RED), label reviewers and registrants may use the suggested storage statements in Attachment B, or develop storage instructions for each product based on the following considerations:

1. Whether the composition or usefulness of the pesticide could be altered by: temperature extremes, excessive moisture or humidity, heat, sunlight, friction, contaminating substances or media that may affect the product.

2. Physical requirements of storage that could affect the container and its ability to function properly: container type, positioning of the container in storage, storage temperature, crushing or damage by stacking, penetration of moisture, and ability to withstand shock or friction.

3. Handling the container: movement within storage area, proper opening and closing procedures (particularly if the container has been opened), and how to minimize exposure while opening or closing the container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions, such as:
   - Lock the storage area, store product in the original container only, or separate products during storage to prevent cross-contamination with other pesticides, fertilizer, food and feed.
   - If it is a residential use product, emphasize keeping the pesticide in the original container and in a locked storage area, and not using an empty container for other uses or substances. *(See PR Notice 83-3)*

D. Additional Guidance on Storage Statements

Websites of state extension services, state and federal agencies and industry associations may offer guidance that is useful for developing storage instructions. Common features include the need for:

- Security - locks, restricted access, frequent inspections for tampering, signage in appropriate languages;
- Recordkeeping - inventory, deliveries, employee licenses, contact and emergency numbers posted;
- Spill prevention and cleanup - emergency response plan, cleanup and first aid supplies; and
- Site integrity - ventilation, lighting, pallets and protection from weather and run on, secondary containment, etc.

V. Pesticide disposal statements

Registrants must provide appropriate instructions on how to dispose of leftover or unused pesticides *(40 CFR 156.10(i)(2)(ix)* and *40 CFR part 156*, Subpart H). Pesticide disposal statements are specific to the uses of the product (e.g., residential or non-residential use) and whether it is a hazardous waste when discarded or "highly toxic".

Listed below are pesticide disposal statements for:

A. Residential use **only** products (including non-antimicrobial residential use) that are not hazardous waste or highly toxic;

B. **Non-**residential use products that are hazardous waste or are highly toxic; and

C. **Non-**residential use products that are not hazardous waste and are not highly toxic.

In sections A, B and C below, language in quotation marks may generally be used verbatim by registrants making label changes by notification.

While Unit V focuses on pesticide disposal statements, some container handling statements are included here for clarity. First, section A shows the pesticide disposal and container handling instructions that are combined for residential use products. These combined pesticide disposal and container handling instructions should appear under the subheading "Pesticide Disposal and Container Handling."

- For non-antimicrobial residential use products, these combined statements were originally provided by *PR Notice 2001-6* (superseded by *PR Notice 2007-1*) and have been updated to reflect the container-containment regulations and *PR Notice 2007-4*.
- For antimicrobial residential use products, the pesticide disposal and container handling instructions that were provided in PR Notices *83-3* and *84-1* are still valid and have been updated to reflect the container-containment regulations. In addition, antimicrobial residential use products can voluntarily use the pesticide disposal and container handling instructions for non-antimicrobial residential use products.

Second, section B includes some adjustments to the container handling instructions that may be appropriate for pesticides that are acute hazardous wastes when discarded.

For non-antimicrobial residential use products, pesticide disposal and container handling instructions are combined and should appear under the subheading "Pesticide Disposal and Container Handling." These statements were originally provided by *PR Notice 2001-6* (superseded by *PR Notice 2007-1*), have been updated to reflect the container-containment regulations and *PR Notice 2007-4*, and are presented in section A below.

For antimicrobial products that are residential use, the pesticide disposal and container handling instructions which were provided in PR Notices *83-3* and *84-1* are still valid, have been updated to reflect the container-containment regulations, and are also presented in section A below. In addition, antimicrobial products that are for residential uses can voluntarily use the pesticide disposal and container handling instructions for non-antimicrobial residential use products.

A. Pesticide disposal and container handling instructions for residential use only products (including non-antimicrobial residential use) that are not hazardous waste or highly toxic

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential Use Product
Pressurized container for any residential use product *(PR Notices 94-2, 2007-1 & 2007-4; 40CFR 156.140(a))* *Note: Because we assume that pressurized containers are aerosol cans, the "Nonrefillable container" and "Do not reuse or refill this container." statements are not required for these containers. (40 CFR 156.140(a)(5)(i))*	"Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions." **Or** "Do Not Puncture or Incinerate! **If empty:** This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to label (DO NOT PUNCTURE!). If recycling option is not available, wrap the container and discard in trash. **If partly filled:** Call your local solid waste agency for disposal instructions."[8]	A pesticide product is considered to be a residential use product if it meets one or both of the following[9]: The intended end use of the product is in or around a residence or household by a resident; **and/or** The product is regularly available to household consumers for purchase, and of a size and type practicable for household use, regardless of
Non-pressurized container for any residential use product PR Notices *2007-1 & 2007-4*; 40 CFR *156.140(a))*	"Nonrefillable container. Do not reuse or refill this container."[10] **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."	

[8] Although the sentence "At present, there are only a few such centers in the country." is consistent with PR Notice 94-2, the Agency recognizes this may no longer be the case. Therefore, it is acceptable for registrants to omit this sentence.

[9] Previously, this referred to "a non-antimicrobial pesticide product". However, PRN *84-1* which has not been superseded for antimicrobial products (section IIB clarification of PRN *83-3* pesticide storage and disposal instructions) says "EPA intended to include under the household use section of the PR Notice, those products which have 'domestic uses,' as defined in 40 CFR 162.3(m)(1-4) and products whose use patterns and container sizes are similar to those defined as 'domestic use'. Thus, for the purposes of this PRN, the definition for household use patterns includes products which are marketed in container sizes similar to products intended for household use and are used in public areas such as office buildings, retails stores, hotels and schools, and hospital patient care areas, as well as products intended for use in home gardens and lawns." In this case, the definition for "household use patterns" could include antimicrobial use pesticides. Therefore, EPA has deleted "a non-antimicrobial pesticide product" so that the definition of residential use applies to antimicrobial and non- antimicrobial products. Also, in this version of Chapter 13, EPA has simplified the phrase "residential/household use" from PR Notice 2007-1 for clarity, particularly when describing the opposite set of products. The phrase "non-residential use" is clearer than "non-residential/household use" or non-residential/non-household use". (See footnote 22 for an explanation of why residue removal instructions are still required for most non-residential use products.)

[10] The statements "Nonrefillable container. Do not reuse or refill this container." are not required for certain container types (See section IV C below). Also, there are other options for the statement "Do not reuse or refill this container." that can be found in *156.140(a)(2)*. Those options are: 1) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state." and 2) if the product is ready-to-use and the directions for use allow a different (similar but concentrated) product to be poured into the container and diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential Use Product
Pressurized or non-pressurized container for **antimicrobial residential/household use products** *(PR Notices 83-3, 84-1 & 2007-4; 40 CFR 156.140(a))*	"Nonrefillable container. Do not reuse or refill this container.[3] Securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available." **Or** "Nonrefillable container. Do not reuse or refill this container.[3] Wrap [container] and put in trash or offer for recycling if available."	whether it is also marketed for agricultural use. *(PR Notice 2007-1)*

Alternative statement for the "If partly filled:" instructions found in section A above

Registrants who voluntarily use a toll-free number or website should:

(1) Put "Call your local solid waste agency or" in front of the toll free number or website address and "for disposal instructions" after, so the statement is "Call your local solid waste agency or (insert toll free number or web site) for disposal instructions."; [Note: some toll free numbers and websites, such as 1-800-CLEANUP and www.earth911.org, may require a licensing agreement. For more information, registrants should contact the organization supporting the toll free number.]
(2) Use a service that is available between 18 – 24 hours per day, free to users, available nationally, gives advice agreeable to the local solid waste authority for the location of the user, and/or provides a direct phone number for the appropriate local or state authority;
and
(3) Reasonably assure that the service will continue to exist at a level that meets user demand.

(PR Notice 2007-1)

B: Pesticide disposal instructions for products not solely for residential use that are hazardous waste; or are highly toxic

Description of pesticide products	Pesticide disposal statements	When a pesticide is a hazardous waste or highly toxic
For products that are **not** solely for residential use and meet any of the criteria in the **far right hand column**.	"Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance."	A pesticide product should bear one of the pesticide disposal instructions in this section if the product: 1) Contains active ingredients that, when discarded, are hazardous waste under the Resource Conservation and Recovery Act (RCRA), *40 CFR 261.33(e) and (f);* 2) When discarded, meets the criteria in *40 CFR 261*, Subpart C for a characteristic waste under RCRA; 3) Is in Toxicity Category I *[DANGER]* on the basis of oral or dermal toxicity, or skin or eye irritation potential; ***or*** 4) Is in Toxicity Category I *[DANGER]* or II *[WARNING]* on the basis of acute inhalation toxicity.
For products that are **not** solely for residential use and the active ingredient **is an acute hazardous waste** per *40 CFR 261.33(e)* *(PR Notice* 83-3) *See the text box below for alternative container handling instructions for pesticides that are acute hazardous waste when disposed.*	"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance."[11]	
For products that are **not** solely for residential use and if either: (1) the active ingredient **is a toxic hazardous waste** per *40 CFR 261.33(f)*; or (2) the product meets any of the criteria in *40 CFR Part 261* Subpart C for a **characteristic hazardous waste** *(PR Notice* 83-3)	"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance."	

[11] PR Notice *83-3* offers this statement for products assigned Toxicity Category I (on the basis of oral or dermal toxicity, skin or eye irritation potential), or Toxicity Category I or II (on the basis of acute inhalation toxicity). However, this statement is misleading for these products since they may not be acute hazardous waste upon disposal.

Alternative Container Handling Instructions for Pesticide Products that are Acute Hazardous Waste When Discarded

Pesticide container handling instructions are described in detail in section IV and Attachment C of this chapter. The following statements can be used (as described below) on the labels of pesticide products that contain active ingredients that, when discarded, are acute hazardous wastes under the RCRA, *40 CFR 261.33(e)*. These statements were originally developed for for certain specific products, but are also appropriate for any pesticide products that are acute hazardous wastes when discarded.

For nonrefillable bags of granular or dry formulation:
Use the appropriate container handling statements as described in Attachment C, Tables C4 (*for nonrefillable paper & plastic bags)* and C8 *(for other non-rigid nonrefillable containers)*, but change the how to clean statement (in e) and the recycling statement (in f1)

from: "...Completely empty bag into application equipment. Offer for recycling if available or..."
to: "...Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or..."

For nonrefillable or refillable plastic or metal containers with a dry flowable or liquid formulation:
Use the appropriate container handling statements as described in Attachment C, Tables C1 (*for nonrefillable metal containers, non-aerosol)*, C3 *(for nonrefillable plastic containers)*, C7 *(for other rigid nonrefillable containers)*, C11 *(for refillable metal containers, non-aerosol)*, C9 *(for refillable plastic containers), and* C13 *(for other refillable containers),* **but add the following language after the recycle, reconditioning and disposal instructions** (in f):

"...If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. DO NOT cut or weld metal containers."*

*(*The last sentence should be used for metal containers, but not for plastic containers.)*

C. Pesticide disposal instructions for products that are <u>not solely</u> for residential use and are <u>not hazardous waste or highly toxic</u>

Description of pesticide products	Pesticide disposal statements
For products not specifically identified in a RED or a PR Notice, that are **not solely** residential use, are **not hazardous wastes**, and are **not highly toxic** (as described above in section B) *Note: The second option may be preferred in some states.* *(PR Notice* 83-3)	"Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility." ***or*** "To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry)."

VI. Container handling statements

A. Subheading

Labels for products in nonrefillable containers must have the appropriate subheadings under the heading "Storage and Disposal" for the statements required by *§156.140(a)* regarding (1) "Nonrefillable container."; (2) container reuse/refill; and (3) container recycling/reconditioning. If placed on the label of a nonrefillable container, these three types of statements must be under an appropriate subheading. EPA recommends that registrants use "Container Handling" rather than "Container Disposal" or similar wording, and that they transition from using "Container Disposal" to "Container Handling". when making other label revisions.

Although a subheading is required only for nonrefillable containers and not refillable containers, EPA recommends using a similar subheading for the container instructions for refillable containers. *(See §156.140(a))*

B. Location

Most container handling instructions are put on the label. However, the container statements required by *§156.140* (identifying the container type, reuse/refill limitations, and information on recycle/reconditioning) can be on the actual container itself as long as the user knows where to find it. For example, under the heading "Storage and Disposal" registrants may put "See container for information on reusing the container" or another appropriate statement. If statements are placed directly on the actual container itself they must be durably marked. Durable marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, a mechanically attached plate, molding, or marking with durable ink. *(See §156.140)* Alternatively, the residue removal instructions and container disposal instructions *must be* on the label under the heading "Storage and Disposal." (PR Notice *83-3*, *§156.10(i)(2)(ix)* and *§156.144*) The batch code can be on the label or the container. *(See §156.140)*

C. Instructions

Container handling instructions should be appropriate for the container type. For example, users should *not* be instructed to puncture or incinerate a pressurized container. In sections C1a through C1f below, language in quotation marks may generally be used verbatim by registrants making label changes by notification. (Exceptions to this are explained on a case-by-case basis.) Optional guidance is provided in brackets. *(See PR Notice 2007-4)*

Is it a *"refillable"* or *"nonrefillable"* container?

The registrant decides based on how the container is intended to be used

A "refillable container" is one that is intended to be refilled for sale or distribution.	A "nonrefillable container" may **not** be refilled for sale or distribution, but in some cases the end user can refill it for use only.

The registrant determines whether a container is "refillable" or "nonrefillable." A refillable container is intended to be filled with pesticide more than once for sale or distribution. A "nonrefillable container" is designed and constructed for one-time use and is not intended to be filled again with a pesticide for sale or distribution. *(See §165.3)*

Products registered solely for residential use are usually sold in *nonrefillable* containers, although occasionally the label instructions allow an end user to refill the container for his/her own use. For example, if a consumer buys a spray bottle filled with a ready-to-use product, uses all of the pesticide up, and buys a 1-gallon bottle with

product to refill the spray bottle, then the spray bottle is a "nonrefillable container" because it is being filled again *for use*, not for sale or distribution. For this to be legal, the instructions on the label of the spray bottle cannot specifically prevent it, e.g., the label of the spray bottle cannot say "Do not reuse or refill this container." and must allow this practice, e.g. "Do not reuse or refill this container except as allowed in the directions for use."

The remainder of this section describes the statements that are required or recommended by EPA regulations or policies. Attachment C shows the full set of appropriate container handling instructions for different types of containers.

If it is a *nonrefillable* container, the label must have:	**If it is a *refillable* container, the label must have:**
A subheading such as "Container Handling" on the label under the heading "Storage and Disposal"; and: a. The nonrefillable container statement b. Reuse limitations c. When to clean (for dilutable pesticides) d. How to clean (for dilutable pesticides) e. Recycle or recondition (and should also have how to dispose) f. Batch code *(See section 1 below)*	a. The refillable container statement b. Reuse limitations c. Who is responsible for cleaning & when d. How to clean The label *should have* container return or disposal instructions. EPA *recommends* that these instructions appear on the label under a subheading such as "Container Handling". *(See section 2 on Refillable Containers)*

1. NONREFILLABLE CONTAINERS

If the pesticide is distributed or sold in a nonrefillable container, the label must have the statements described below unless otherwise exempted, modified or waived with EPA approval. If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§*156.140* – 156.156 or if otherwise allowed by EPA.

1a. Nonrefillable container and 1b. Reuse limitations

The phrase "Nonrefillable container." and one of the reuse limitations are required on the label ***except if:***

- The product is a plant-incorporated protectant, pesticidal article not already exempted under *§152.25(a)* or distributed only in a transport vehicle *(See §156.140*, and *§156.140(d)&(e)).*
- EPA requires a different statement or approves a modification or waiver requested by the registrant.
- The product and/or container type is listed in Table 1 *(See §156.140(a)(5)).*

Table 1. Exemptions to the Requirement for "Nonrefillable container" Statement and Reuse Limitations on the Label

Exemption *(§156.140(a))*	Example
(i) Aerosol can	Bug spray (insecticide) in aerosol can
(ii) Device as defined in *§152.500*	Mouse trap
(iii) One-time use caulking tube or other one-time use squeezable tube container for paste, gel or other similar substance	Crack & crevice treatment gel in syringe applicator; Pet product gel in squeezable tube
(iv) Foil packet for water soluble packaging, repellent wipes, or other one-time use products	Foil or plastic pouches around water-soluble film holding a dose of pesticide; Foil packet with gel strip for wood treatment; Pouch around mosquito repellent coils
(v) One-time use portion control packet, such as a polyethylene sleeve package or rodenticide place pack	Portion pack with sanitizer; Plastic pouch for swimming pool tablet; Plastic pouch for disinfecting wipes (and refill pack for user); Plastic pouch for toilet bowl cleaner tablet
(vi) One-time use bait station	Bait station for rodenticide product
(vii) One-time use cage for repellent or trapping strip	Cage containing sticky strip with insecticide
(viii) Pet collar or animal ear tag, such as for cattle	Flea collar for pets
(ix) One-time use semiochemical dispersion device	A polymeric dispenser (2 tubes fused together) that can be hung from a tree branch and contains a pheremone
(x) Any container that is destroyed by the use of the product contained	Shrink wrap on block of cattle feed
(xi) Any container that would be destroyed if reuse of the container were attempted	Roll-on fly repellent; Cassette containing sterilant for hospital equipment; Closed, sonic-sealed dispensing systems used in industrial and institutional settings

Registrants should consult with the EPA Product Manager if they are uncertain whether a product fits into one of the categories in Table 1 above.

1a. The phrase "Nonrefillable container." and 1b. Reuse limitations on nonrefillable containers *(See §156.140(a)(1)&(2))*

When the "Nonrefillable container." phrase and a reuse limitation statement are both required for a pesticide in a nonrefillable container, registrants must use one of the following options:

i. "Nonrefillable container. Do not reuse or refill this container."

ii. "Nonrefillable container. Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

iii. For a ready-to-use product that has directions for use that allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Nonrefillable

container. Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." (*Note: In some situations, EPA has waived the requirement to include the phrase "Nonrefillable container." if this set of reuse limitations is used.*)

iv. An acceptable variation of 1.b.iii. is: [Nonrefillable container. Do not reuse or refill this container except as allowed in the directions for use.] In this case, the directions for use must describe how to refill the container and with what product(s). *(Note: This set of instructions is not in quotation marks because it is not verbatim from the regulations. It is up to the EPA reviewer and/or PM whether it can be accepted via notification or amendment. Also, in some situations EPA has waived the requirement to use the phrase "Nonrefillable container." when this set of reuse limitations is used.*)

1c. and 1d. Cleaning instructions Cleaning instructions are required on the label if the nonrefillable container is rigid and the product is dilutable EXCEPT

if the product is a:

- Residential[12] use only;
- Gas at atmospheric conditions;
- Pesticidal article that is not already exempted by *§152.25(a)*; and
- Pesticide distributed only in transport vehicles.

(Exempt by regulation. See 40 CFR 156.144)

In addition, EPA may require a different statement or approve a modification or waiver requested by the registrant. Note: If a nonrefillable container is not rigid or the product is not dilutable, or both, cleaning instructions (both when and how) are not required. Preferred cleaning instructions for non-rigid container types such as bags can be found in PR Notice 83-3 (e.g., "Completely empty bag into application equipment.") and in the appropriate tables in Attachment C.

[12] More information on residue removal requirements for non-residential antimicrobial products can be found in footnote 22.

What is a "dilutable" pesticide?

For the purposes of the container-containment regulation, a dilutable pesticide is one for which "...the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use." *(§156.3)*

A pesticide applied directly to swimming pool water is ***not*** a dilutable pesticide because it is not mixed with a diluent before it is added to pool water.

Similarly, many manufacturing use products are ***not*** dilutable because they are not mixed with a diluent before they are used to formulate a product, although it depends on the specific directions for use on the label.

1c. When to clean rigid, nonrefillable containers of dilutable pesticides

The options are:

i. "Clean container promptly after emptying."

ii. "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."

iii. "Triple rinse container (or equivalent) promptly after emptying."

(See §156.146(a))

Registrants using option 1.c.ii (above) must give triple rinse instructions, immediately followed by pressure rinse instructions.

1d. How to clean rigid, nonrefillable containers of dilutable pesticides

For dilutable pesticides in rigid nonrefillable containers, the label must include triple rinse instructions unless EPA waives the requirement. The options for **triple rinse** instructions for rigid, nonrefillable containers with dilutable pesticides are:

i. For liquid dilutable pesticides in rigid, nonrefillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons), "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

ii. For solid dilutable pesticides in rigid, nonrefillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons or 50 pounds), "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

iii. For any dilutable pesticides in rigid, nonrefillable containers too large to shake (i.e., with capacities more than 5 gallons or 50 pounds), "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30

seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

(See §156.146(b))

iv. For antimicrobial products with public health claims that are dilutable pesticides in rigid, nonrefillable containers EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:

In containers small enough to shake (i.e., with capacities equal to or less than 5 gallons or 50 pounds), "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."

In containers too large to shake (i.e. with capacities more than 5 gallons or 50 pounds),"Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times."

v. For seed treatment products in rigid, nonrefillable containers, EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:

Triple rinse as follows: *For containers with capacity equal to or less than 5 gallons:* Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume, and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

For containers with capacities greater than 5 gallons: Empty the remaining contents into application equipment or a mix tank. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

The options for **pressure rinse instructions** for rigid, nonrefillable containers of dilutable pesticides are:

vi. For liquid dilutable pesticides in rigid, nonrefillable containers, "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

vii. For solid dilutable pesticides in rigid, nonrefillable containers, "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(See §156.146(c))

Registrants who want to use a non-water diluent must submit a request to EPA explaining why a diluent other than water is necessary, what the diluent is, and the instructions that would be used for cleaning the container and disposing of the rinsate.

Registrants may not distribute or sell the pesticide with modified residue removal instructions (using a non-water diluent) until EPA approves the request in writing. *(See §156.146(d))*

1e. Recycle, recondition, or dispose

The label of a pesticide product in a nonrefillable container must have instructions on whether to recycle or recondition nonrefillable containers *except for* plant-incorporated protectants, pesticidal articles not already exempted under *§152.25(a),* and pesticides distributed only in transport vehicles, or if EPA requires a different statement or approves a modification or waiver requested by the registrant. In addition, the label should include instructions for disposing of the container if recycling or reconditioning is not an option. *(See §156.140(a)(3)* and *PR Notice* 83-3*)*

The options for **container recycling/reconditioning** *(§156.146(a)(3))* are:

i. "Offer for recycling if available or *[disposal statement]*."

ii. "Offer for reconditioning if appropriate or *[disposal statement]*."

iii. If it is an agricultural product: "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [*a pesticide container recycling organization*] at [*phone number*] or [*web site*] or *[disposal statement]*." *[An example of a pesticide container recycling organization, phone number or web site is: Ag Container Recycling Council at 1-877-952-2272 or* www.acrecycle.org*]*

iv. A recycling statement published in an EPA document, such as a PR Notice.

v. A recycling statement reviewed and approved by EPA.

The options for **disposing** of the container are: *[to follow one of the statements from i. through v above]*

...place [or put] in trash or in a sanitary landfill.

...dispose of in trash or in a sanitary landfill or by incineration.

...dispose of in trash or in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

...dispose of in trash or in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances.

...dispose of in trash or in a sanitary landfill or by incineration. In most states, burning is not allowed.

1f. Batch code

The batch code is required on all nonrefillable containers ***except for*** plant-incorporated protectants, pesticidal articles not already exempted under *§152.25(a)* and pesticides distributed solely in transport vehicles. It may be a lot number, or other code used by the registrant or producer to identify the batch of the product distributed or sold. *(See §156.140(a)(4))* In a situation where multiple containers are sold in one box, each container must have a batch code unless EPA approves a request (with a justification) to modify or waive the requirement.

2. REFILLABLE CONTAINERS

If the pesticide is distributed in a refillable container, the label,	
MUST HAVE:	2a. The refillable container statement 2b. Reuse limitations 2c. Who is responsible for cleaning and when 2d. How to clean
AND SHOULD HAVE:	2e. Return and/or disposal instructions

If the pesticide is distributed or sold in a refillable container, the label must have the statements described below unless otherwise exempted, modified or waived with EPA approval. If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§*156.140* – 156.156 or if otherwise allowed by EPA.

2a. Refillable container and 2b. Reuse limitations

2a. The statement "Refillable container" and **2b.** Reuse limitations are required on the label of all refillable containers ***except for*** plant-incorporated protectants, pesticidal articles not already exempted under *§152.25(a)*, and pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant.

The options are:

i. "Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose."

ii. "Refillable container. Refill this container with [common chemical name] only. Do not reuse this container for any other purpose."

Unlike nonrefillable containers, the labels of refillable containers must have cleaning instructions whether or not the container is rigid and/or the product is dilutable.

2c and 2d Cleaning instructions

2c. Statements about who is responsible for cleaning a refillable container & when are required on the label of all refillable ***except for*** pesticidal articles not already exempted under *§152.25(a),* pesticides that are gases under atmospheric conditions, residential/household use products and pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant. *(See §156.144(c) through (g))*

The options are:

i. "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller." *(Triple rinsing or pressure rinsing instructions follow.); or*

ii. "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller." *(Pressure rinsing instructions follow.)*

(See §156.156(a))

2d. Instructions on **how to clean a refillable container are** required ***except for*** products that are pesticidal articles not already exempted under *§152.25(a),* gases under atmospheric conditions, residential/household use or pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant. *(§156.144(c) through (g))*

Instructions for removing residue from refillable containers prior to disposal must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment. *(See §156.156(b))*

The options are:

i. For pesticides that require dilution prior to application, the following statement can be used: "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."

ii. A procedure developed by the registrant for that product;

iii. Standard industry practices for refillable containers; or

iv. Any other statement the registrant considers appropriate and EPA accepts.

v. For seed treatment products in rigid, nonrefillable containers, EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:
To clean the container before final disposal, empty the remaining contents into application equipment or mix tank. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume. Replace and tighten closure. Agitate vigorously or recirculate the rinsate with a pump for at least 2 minutes, ensuring that the rinsate rinses the walls of the container. Empty the rinsate into application equipment or rinsate collection system, for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

2e. Instructions on how to **return or recycle/dispose of refillable containers should be on refillable containers.**

The options for the return of **refillable containers are:**

i. When empty, return to point of sale.

ii. Call 1-800-XXX-XXXX for instructions on returning the empty container.

iii. Any other statement reviewed and approved by EPA.

The options for disposal of **refillable containers depends on the product and type of container.**

One example is:

...or puncture or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

See Tables C1 through C15 below for appropriate disposal instructions.

VII. Multiple container handling statements on one label

Each pesticide product must bear storage and disposal statements appropriate for its container. The registrant may submit separate labels for each container type and/or size, or may submit a single label with alternative storage and disposal statements. A label submitted for EPA review that bears multiple statements must indicate the circumstances in which each statement would appear on a final container label. For example, a label may indicate in italics and/or brackets that one section of the container handling and disposal instructions are for plastic containers with a capacity of 5 gallons or less while another section is for plastic containers greater than 5 gallons. The proposed labels will be reviewed by the appropriate EPA Product Manager or the Notification Team and approved if acceptable.

Example of Container Handling Instructions for Multiple Container Types, Sizes and Uses*

Container Handling
(For Residential uses)
Nonrefillable container. Do not reuse or refill this container. If empty: Offer for recycling if available or discard in a sanitary landfill. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

(For Commercial Uses)
For plastic containers less than or equal to 5 gallons: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

For plastic containers greater than 5 gallons: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Recap and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

**This example is for a dilutable product, distributed or sold in a rigid, nonrefillable container.*

Preferably, a label that appears on or is securely attached to the immediate container will have instructions only for that container. However, it may be acceptable for a pesticide product label to have container handling/container disposal instructions for multiple container types in which that product can be sold, provided that the presentation of the instructions is sufficiently clear to the end user. The end user must be able to read, understand, and identify which instructions to use under customary conditions of purchase and use, and not detract from other label provisions. If an end user cannot tell which set of container handling/container disposal instructions to follow, the pesticide would be misbranded.

Some labels have alternative handling/disposal statements that were approved under the assumption that end users knew that 1- and 2.5-gallon containers are not ordinarily intended to be refillable. Thus, those labels did not specifically identify the containers as non-refillable and did not specifically exclude 1- and 2.5-gallon containers from the refillable container instructions. However, in order to facilitate the use of 1- and 2.5-gallon refillable containers in the future, EPA intends to ask registrants to revise these labels to identify whether containers are refillable or non-refillable when other label changes are proposed. During the review of future label amendments, EPA will also look for situations and ask for clarification where multiple handling/disposal instructions might be confusing and appear to apply to only one container type and/or size.

ATTACHMENT A

Pesticide Storage Statements for Products with Certain Active Ingredients

Historically, EPA has developed specific storage instructions for certain active ingredients. Table 2 below shows some examples. However, these ***may not be the complete*** *storage instructions*. Registrants should check with EPA Product Managers and follow the guidance provided in this chapter for the complete the storage instructions. Examples of requirements that may not be provided in Table 2 for all active ingredients include, but are not limited to:

- All instructions must appear under the heading "STORAGE AND DISPOSAL".
- Products sold for non-residential use must have the statement: "Do not contaminate water, food, or feed by storage or disposal."
- Products distributed or sold in nonrefillable containers must have, and refillable containers are suggested to have, a subheading under the heading "STORAGE AND DISPOSAL". EPA recommends that when making label revisions registrant transition to using "Container Handling"

Although Table 2 contains mostly storage instructions, product disposal and container handling instructions may also be provided for some active ingredients. Registrants should check the information provided in this chapter for the most recent and complete storage and disposal instructions. Statements in bold indicate language added to comply with the regulations at *40 CFR §156.140*.

Table 2. Preferred Active-Ingredient Specific Pesticide Storage Statements

Active Ingredient	Pesticide Storage Statements[13]	Source of Statement
Liquid calcium hypochlorite and Liquid sodium hypochlorite	" Do not contaminate food or feed by storage, disposal, or cleaning of equipment. Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer."[14]	*PR Notice 84-1 & errata sheet, 40 CFR 156.140,* and *PR Notice 2007-4*

[13] Not all instructions provided in this table are the complete storage and disposal instructions required for the active ingredient shown.

[14] See Attachment D for a sample of complete container handling instructions for calcium hypochlorite (solid and liquid) and liquid sodium hypochlorite. Also, the last sentence was revised from "should be diluted" to "must be diluted". The Agency recommends making this change during label amendments or other actions submitted after Chapter 13 is posted on the web site.

Active Ingredient	Pesticide Storage Statements[13]	Source of Statement
Solid calcium hypochlorite	"Keep this product dry in a tightly closed container when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all materials before discarding this container. [15]	*PR Notice 84-1 & errata sheet, 40 CFR 156.140,* and *PR Notice 2007-4*
Etridiazole	Manufacturing use products must contain the statement "This product is corrosive to steel and many other metals. Do not transport or store in unlined metal containers." *(Note: these statements take precedence over the storage guidelines in the PR Notice for manufacturing use products only.)*	*PR Notice 84-1*
Methyl bromide and Methyl bromide plus 2% or less chloropicrin	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food, or feed by storage. Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders using hand truck, fork truck or other device to which the cylinder can be firmly secured. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders."	*PR Notice 84-5*

[15] See Attachment D for a sample of complete Storage and Disposal instructions for calcium hypochlorite (solid and liquid) and liquid sodium hypochlorite.

Active Ingredient	Pesticide Storage Statements[13]	Source of Statement
Aluminum phosphide and Magnesium phosphide	"Not for use or storage in or around inhabited areas. Protect from moisture, open flames, and heat. Store in a dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store container away from all liquids. Store so as to minimize hazards of tipping, spilling or accidental puncturing of the container. Keep container tightly closed when not in use. Do not contaminate water, food, or feed by storage or disposal."	*PR Notices 84-5* and *84-1*
Chloropicrin	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food, or feed by storage or disposal. Persons moving or handling containers should wear protective clothing. Open container only in a well-ventilated area wearing protective clothing, and respiratory protection if necessary."	*PR Notice 84-5*
Sodium cyanide	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store container away from all liquids. Store so as to minimize hazards of tipping, spilling or accidental puncturing of the container. Keep container tightly closed when not in use. Do not contaminate water, food, or feed by storage or disposal."	*PR Notice 84-5*
Ethylene oxide	"Do not contaminate water, food, or feed by storage. Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders using hand truck, fork truck or other device to which the cylinder can be firmly secured. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders."	*PR Notice 84-5*

Sulfuryl fluoride[16]	" **Storage and Disposal** Do not contaminate water, food, or feed by storage or disposal. **Pesticide Storage** Store in dry, cool, well ventilated area under lock and key. Post as a pesticide storage area. If the storage area is in an occupied building, the storage area must have either 1) a forced air ventilation system that meets required local ordinances for the storage of hazardous materials and operates continuously; or 2) be equipped with a permanently mounted and properly maintained and functioning sulfuryl fluoride monitoring device designed to alert occupants of the building if sulfuryl fluoride in the air of the storage area is greater than 1 ppm. Store cylinders upright, secured to a rack or wall to prevent tipping. **Pesticide Handling:** Cylinders must not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding beyond that which would normally occur when moving cylinders. Do not transport any cylinders in closed vehicles where they occupy the same common airspace as personnel. Transport securely only in an upright position. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to supplier. Only the registrant is authorized to refill cylinders. Do not use cylinder for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders. **Leak Procedures:** Evacuate immediate area of leak. Use a NIOSH or MSHA approved positive pressure self-contained breathing apparatus (SCBA, not SCUBA) or combination air-supplied/SCBA respirator, such as manufactured by Ranger, Survivair, Scott, or MSA, for entry into affected areas to correct problem. Move leaking or damaged cylinder outdoors or to an isolated location, observing strict safety precautions. Work upwind if possible. Do not permit entry into leakage area by unprotected persons until concentration of fumigant in the breathing zone (areas within the structure where individuals typically stand, sit or lie down) is determined to be 1 part per million (ppm) or less, as determined by a detection device with sufficient sensitivity such as an INTERSCAN, MIRAN [SapphiRe] or Spectros ExplorIR gas analyzers. For more detailed information on the source and use of air monitoring devices or respirators, consult the Vikane Gas Fumigant Structural Fumigation Manual. **Cylinder and Product Disposal:** Refillable container. Refill this container with pesticide only. Do not use this container for any other purpose. Promptly return all empty cylinders to your distributor of this product. Follow proper cylinder handling directions above. Pesticide wastes may be hazardous. Improper disposal of excess pesticide is a violation of	*PR Notice 84-5*

[16] The language for sulfuryl fluoride is suggested, rather than preferred, by EPA. Storage instructions in PR Notice 84-5 were updated by RD on 6/5/12 to bring it up to compliance with PR Notice 2007-4.

	Federal law. If these wastes cannot be disposed of by use according to label instructions, consult your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.	

ATTACHMENT B

Storage Statements Suggested by EPA

The following are examples of storage statements that registrants may use for products with active ingredients not listed in *Attachment A*. EPA provided these suggested statements as a result of a recommendation from the State FIFRA Issues Research and Evaluation Group. Some of these may not be appropriate for all pesticide products.

"Always store pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents."

"Storage areas must be locked and secure from vandalism, with precautionary signs posted."

"The storage area must be dry, well-lit, and well-ventilated. Keep pesticide storage areas clean. Clean up any spills promptly."

"Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies."

"Protect pesticide containers from extreme heat and cold."

"Store herbicides, insecticides and fungicides in separate areas within the storage unit."

"Place liquid formulations on lower shelves and dry formulations above."

"Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergencies."

"If spill cleanup PPE is stored nearby, but outside the pesticide storage area, it will be accessible when needed."

ATTACHMENT C

Container Handling Instructions by Container Type

The following tables show the full set of appropriate container handling instructions by different container types. In each table, the first column describes which of the statements, if any, are required and under what conditions. The second column describes the general category of the statements, using the categories described in Unit IV.C of Chapter 13. The last columns on the right show the specific language to include on the pesticide label. Areas shaded in gray indicate that the statement it is not required for that container type. In a situation where a specific container type is not listed, see the appendices to PR Notice *2007-4* and/or one of the following tables below for guidance: Table A7 (for other rigid nonrefillable containers); Table A8 (for other non-rigid nonrefillable containers); or Table B5 (for other refillable containers).

List of Tables

Table C1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required *unless* product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type*** ***and*** ***c. Reuse limitations of container***	[b] "Nonrefillable container. "
		[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is ready-to-use and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for non-residential use only if product is dilutable **Use** one option from d1, d2 or d3, followed	***d. When to clean***	[d1] "Clean container promptly after emptying."
		[d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must give instructions for triple rinsing immediately followed by pressure rinsing instructions)*
		[d3] "Triple rinse container (or equivalent) promptly after emptying."

Table C1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
by one option from e1, e2, e3 or e4 *A "dilutable" product is mixed with a diluent by the end user before use or application* *Registrants who wish to use a diluent other than water must contact EPA for approval*	***e. How to clean***	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e3] For any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."
		[e4] For *antimicrobial products with public health claims for dilutable pesticide in rigid, nonrefillable containers]:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."

Table C1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
e5 and e6 are ***requiredif*** *d2is used above, otherwise,it is optional to add e5 or e6 after e1, e3 or e4*		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
		[e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2 or f3	***f. Recycle + dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."
		[f3] "Then offer for reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C2: Container Handling Statements for NONREFILLABLE AEROSOL CANS

Registrants may request a waiver or modification from EPA for any of the requirements. Please note that while these statements are from PR notices that address household or residential use products, the Agency is recommending the same statements for all other aerosol products.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Exempt per §156.140(a)(5) *(See unit IV.C.1a or Table 1 of this chapter)*	***b. Container type***	
	and	
	c. Reuse limitations of container	
Not required because product is not dilutable *(Also not required for residential uses or products that are gases)*	***d. When to clean***	
	and	
	e. *How to clean*	
Required **Use** f1 or f2	***f. Recycle or dispose and pesticide disposal***	[f1] Do Not Puncture or Incinerate! If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions." [f2] "Do Not Puncture or Incinerate! If empty: This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country.[17] Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling option is not available, discard in the trash. If partly filled: Call your local solid waste agency for disposal instructions."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

[17] Although the sentence "At present, there are only a few such centers in the country." is consistent with PR Notice 94-2, the Agency recognizes this may not longer be the case. Therefore, it is acceptable for registrants to omit this sentence.

Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required *unless* product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** b followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is ready-to-use and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for non-residential /household use only if the product is dilutable **Use** one option from d1, d2 or d3 followed by one option from e1, e2, e3 or e4	***d. When to clean***	[d1] "Clean container promptly after emptying." [d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must have instructions for triple rinsing immediately followed by pressure rinsing instructions.)* [d3] "Triple rinse container (or equivalent) promptly after emptying.
Registrants who want	***e. How to clean***	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less)

Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
to use a diluent other than water must first get EPA approval *A "dilutable" product is mixed with a diluent by the end user before use or application*		"Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times." [e2] For solid dilutables in containers small <u>enough to shake</u> (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times." [e3] For any dilutable pesticide in <u>containers too large to shake</u> (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times." [e4] For *<u>antimicrobial products</u> with public health claims for dilutable pesticide in rigid, nonrefillable containers]:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."

Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required, but if d1 or d3 is used, registrants may add e5 or e6 after e1, e2, e3 or e4		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip." [e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2, f3 or f4	***f. Recycle + dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration."
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration."
		[f3] "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact [a pesticide container recycling organization] at [phone number] or [website], or puncture and dispose of in a sanitary landfill, or by incineration."
		[f4] "Then offer for reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration."
Not required, but registrants may add f5, f6 or f7 after f1, f2, f3 or f4		[f5] ..."or if allowed by state and local authorities, by burning. If burned, stay out of smoke." [f6] ..."Do not burn, unless allowed by state and local ordinances."

Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[f7] ..."In most states, burning is not allowed."
Required anywhere on label or on container	***g. Batch code***	*A lot number, or other code used by the registrant or producer to identify the batch.*

Table C4: Container Handling Statements for NONREFILLABLE PAPER and PLASTIC BAGS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required *unless* product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** b followed by one option from c1 or c2	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, its directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*

Table C4: Container Handling Statements for NONREFILLABLE PAPER and PLASTIC BAGS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required because the nonrefillable container is not rigid *(Also not required for residential uses or products that are gases)*	***d. When to clean***	
Required *except for* residential use (PRN 83-3) **Use** [e1]	***e. How to clean and Recycle +dispose***	[e1] "Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration."
Not required, but registrants may add e2, e3 or e4 after e1		[e2] ..."or if allowed by state and local authorities, by burning. If burned, stay out of smoke." [e3] ..."Do not burn, unless allowed by state and local ordinances." [e4] ..."In most states, burning is not allowed."
Required anywhere on label or on container	***f. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C5: Container Handling Statements for NONREFILLABLE FIBER DRUMS with LINERS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required *unless* product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilutable pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is "ready-to-use" and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid	***d. When to clean***	
Required **Use** [e]	***e. How to clean***	[e] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment."
Required **Use** f1 followed by f5 *Not required, but registrant may add f2, f3 or f4 in between f1 and f5*	***f. Recycle + dispose***	[f1] "then offer for recycling if available or dispose of in a sanitary landfill or by incineration"...
		[f2] ..."or if allowed by state and local authorities, by burning. If burned, stay out of smoke."
		[f3] ..."Do not burn, unless allowed by state and local ordinances."
		[f4] ..."In most states, burning is not allowed."

		[f5] "If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner." *(* A registrant may replace this phrase with one indicating whether & how fiber drum may be reused.)*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C6: Container Handling Statements for NONREFILLABLE FOIL OUTER POUCHES of WATER SOLUBLE PACKETS (WSP)

Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)*	***b. Container type and c. Reuse limitations of container***	
Not required because the nonrefillable container is not rigid	***d. When to clean and e. How to clean***	
Required **Use** f	***f. Recycle + dispose***	[f] "Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C7 Container Handling Statements for OTHER RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles no already exempted by ***40 CFR §152.25(a)*** are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	**Type of Statement**	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required *unless* the product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container."
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."*(May use if product is ready-to-use, directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use."*(May use if the product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for uses other than residential/house-hold use **only if** the product is dilutable Use one option from d1, d2 or d3	***d. When to clean***	[d1] "Clean container promptly after emptying."
		[d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must have instructions for triple rinsing immediately followed by pressure rinsing instructions.)*
		[d3] "Triple rinse container (or equivalent) promptly after emptying."

Table C7 Container Handling Statements for OTHER RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles no already exempted by ***40 CFR §152.25(a)*** are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	**Type of Statement**	Specific Statements to Include on the Label
Use one option from d1, d2 or d3 followed by one option from e1, e2, e3 or e4 *A "dilutable" product is mixed with a diluent by the end user before use or application* *Registrants who want to use a diluent other than water must first get EPA approval*	***e. How to clean***	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e3] For any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

Table C7 Container Handling Statements for OTHER RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles no already exempted by ***40 CFR §152.25(a)*** are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	**Type of Statement**	Specific Statements to Include on the Label
Not required but if using d1 or d2, registrants may add e5 or e6 after e1, e2, e3 or e4		[e4] For *antimicrobial products with public health claims for dilutable pesticide in rigid, nonrefillable containers:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."
		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Emptythe remaining contents into application equipment or a mix tank and continue to drain for 10seconds after the flow begins to drip. Hold container upside down over application equipmentor a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
		[e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2 or f3	***f. Recycle, recondition or dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f3] "Then offer for reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C8 Container Handling Statements for OTHER NON-RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required *unless* the product and/or container type are exempt per *§156.140(a)(5)* *[See unit IV.C.1a or Table 1 of this chapter]* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container."
	c. Reuse limitations for container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if ready-to-use and directions for use allow a different product (similar but concentrated) to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, its directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid. *(Also not required for residential use)* (*§156.146*)	***d. When to clean***	
May be required *except for* residential/ household use (PRN *83-3*)	***e. How to clean***	*See the "How to clean" instructions for paper or plastic bags and fiber drums with liners for potentially applicable cleaning or emptying instructions from* PR Notice 83-3.

Table C8 Container Handling Statements for OTHER NON-RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required **Use** one option from f1, f2 or f3	***f. Recycle, recondition or dispose***	[f1] "Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f2] "Offer for recycling if available or reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f3] "Offer for reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		**Note that "or by other procedures approved by state and local authorities" is a basic container disposal statement that is likely to apply to many types of containers. For other options, see the specific container disposal statements for nonrefillable metal, plastic, paper/plastic bags, and fiber drums with liners.*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table C9 Container Handling Statements for REFILLABLE METAL Containers (non-aerosol)

Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required *except for* plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required *except for* products that are gases and for residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"...
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"...
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] *[For pesticides that require dilution prior to application, the following statement*:]* ..."empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*
Not required but recommended	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] *[Any other return statement the registrant considers appropriate.]*

Table C9 Container Handling Statements for REFILLABLE METAL Containers (non-aerosol)

Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Use f1 or f2 followed by f3 or f4		[f3] ..."or offer for recycling if available or reconditioning if appropriate"... or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities." [f4] ... "or offer for recycling if available"... "or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

Table C10 Container Handling Statements for REFILLABLE PLASTIC Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)*and pesticides distributed only in transportation vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required *except for* plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required *except for* products that are gases or residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] *[For pesticides that require dilution prior to application, the following statement:*]* "Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*]*

Table C10 Container Handling Statements for REFILLABLE PLASTIC Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* and pesticides distributed only in transportation vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		* *The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*
Not required but recommended **Use** f1 or f2 followed by f3 or f4, then f5	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] *[Any other return statement the registrant considers appropriate.]* [f3] "Then offer for recycling if available"... [f4] "Then offer for recycling if available or reconditioning if appropriate"... [f5] ..."or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved state and local authorities."

Table C11 Container Handling Statements for REFILLABLE FIBER DRUMS WITH LINERS

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required *except for* plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required *except for* products that are gases and for residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when and*** ***e. How to clean***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"...
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"...
		[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix tank."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*

Table C11 Container Handling Statements for REFILLABLE FIBER DRUMS WITH LINERS

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended **Use** f1 or f2, followed by f3 or f4, followed by f5 or f6, then f9 *May insert f5 or f6 in front of f9*	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] *[Any other return statement the registrant considers appropriate.]* [f3] "or offer for recycling if available"... [f4] "or offer for recycling if available or reconditioning if appropriate"... [f5]..."or dispose of in a sanitary landfill, or by incineration, or if allowed by local and state authorities, by burning. If burned, stay out of smoke." If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. [f6] ..."or dispose of in a sanitary landfill, or by incineration." If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. [f7] "Do not burn unless allowed by state and local ordinances." [f8] "In most states, burning is not allowed." [f9] "If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. **A registrant may replace this phrase with one indicating whether and how the fiber drum may be reused.*

Table C12 Container Handling Statements for REFILLABLE COMPRESSED GAS CYLINDERS

Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements for REFILLABLE COMPRESSED GAS CYLINDERS	
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]	
Required Use [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."	
	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."	[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Contact the EPA Product Manager to determine whether cleaning instructions are needed	***d. Who is responsible for cleaning and when and e. How to clean***	To be determined on a product-specific basis.	
Required Use f1 or f2	***f. Return, recycle or disposal***	[f1] "Return empty cylinder for reuse."	[f2] [*Other wording similar to f1.]*

Table C13 Container Handling Statements for OTHER REFILLABLE Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required *except for* plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required *except for* products that are gases and for products that are residential/ household use products Use d1 or d2 followed by one option from e1, e2, e3, or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] [*For pesticides that require dilution prior to application, the following statement:*]* "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*] * The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*

Table C13 Container Handling Statements for OTHER REFILLABLE Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended **Use** f1 or f2 followed by f3 or f4, then f5	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] [Any other return statement the registrant considers appropriate.] [f3] "Or offer for recycling if available"... [f4] "Or offer for recycling if available or reconditioning if appropriate"... [f5] ..."or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities." [f5] ..."or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities." [f5] ..."or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

ATTACHMENT D – Sample Storage and Disposal Language for Antimicrobial Pesticides with (Part I) Liquid Sodium and Calcium Hypochlorites as well as (Part II) Solid Calcium Hypochlorite

Part I. Products with Liquid Sodium Hypochlorite or Liquid Calcium Hypochlorite[18]

For Residential use:
"STORAGE AND DISPOSAL
Do not contaminate food or feed by storage, disposal, or cleaning of equipment.[19]
STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.
PESTICIDE[20] DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.
CONTAINER HANDLING[21]: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash.

For Institutional/Commercial use:
"STORAGE AND DISPOSAL
Do not contaminate food or feed by storage, disposal, or cleaning of equipment.
STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.
PESTICIDE DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.
CONTAINER HANDLING:
[If the container is nonrefillable, use the first line ("Nonrefillable..."), the appropriate rinsing instructions for the container size and the next line ("Offer for..."). If the container is refillable, use the paragraph beginning with "Refillable container."]

Nonrefillable container. Do not reuse or refill this container.

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[18] This sample language has been accepted for a liquid sodium hypochlorite product. However, because there are other options available for cleaning and container disposal instructions, registrants should work with EPA reviewers to determine the most appropriate language for any given product. Also, registrants should use only the instructions that apply to their container type, uses and sizes. For example, if a registrant does not distribute or sell a product in a refillable container, they may omit those instructions. This language should be used as a model for changes made during label amendments or other actions after Chapter 13 is posted on the web site.

[19] Although the Agency has historically required the statement "Do not contaminate water, food, or feed by storage and disposal." for all products except residential use products, this sentence is required for all residential and non-residential use products with sodium and calcium hypochlorite salts per the errata sheet for PR Notice 84-1.

[20] Registrants may request EPA reviewers to replace the word "pesticide" with "product", especially for products with residential uses. If it were accepted, the same change would also have to be made to "Follow Pesticide Disposal..." in the residue removal instructions. In accordance with PR Notice 2000-5, directions which are necessary for the safe handling of a pesticide product need to be mandatory and not advisory. Therefore, the phrase "should be diluted" needs to be changed to "must be diluted". The Agency recommends making this change during label amendments or other actions after Chapter 13 is posted on the web site.

[21] The language that follows "CONTAINER HANDLING" has been revised from the PR Notice 84-1 errata sheet so that it complies with the pesticide container labeling requirements in 40 CFR 156.140 – 156.159.

(For dilutable[22] products in containers 5 gallons or less) Clean container promptly after emptying. Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

(For dilutable products in containers larger than 5 gallons) Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times.

Offer for recycling if available or reconditioning if appropriate or place in trash.

Refillable container. Refill this container with pesticide [or common chemical name] only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Offer container for recycling if available or reconditioning if appropriate or place in trash."

Part II. Products with Solid Calcium Hypochlorite[23]

For Residential use:
"STORAGE AND DISPOSAL
Do not contaminate food or feed by storage, disposal, or cleaning of equipment.[24]
STORAGE: Keep this product dry in a tightly closed container when not in use. Store in a cool dry well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all materials before discarding this container.
PESTICIDE DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.
CONTAINER HANDLING[25]: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash.

[22] There is confusion regarding "residential use" vs. "institutional use." PR Notice 84-1 only addresses container storage, pesticide product disposal, and in a couple of cases, pesticide container disposal. It does not address residue removal instructions. It explains that "For purposes of this PR Notice..." when products are distributed or sold in a container in the same sizes for institutional uses as they are for residential uses, the labels may have the same storage and disposal instructions provided in the notice. The requirements for residue removal instructions in §§156.140 through 156.156 were put in place in 2006, well after PR Notice 84-1. Although §156.144 exempts products with residential uses from the requirement to have residue removal instructions, the size of the container is not a factor in determining whether residue removal instructions are required. Furthermore, the definition of "residential use" in §152.5 is:"use of a pesticide directly: (1) On humans or pets, (2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or (3) In any preschool or day care facility." Therefore, residue removal instructions (a.k.a."cleaning instructions") are required for non-residential uses distributed or sold in all refillable containers as well as for rigid nonrefillable containers with dilutable products. *(Note: there are some exceptions that can be found in §156.144.)*

[23] The same footnotes provided above apply to these instructions as well.

[24] Although the Agency has historically required the statement "Do not contaminate water, food, or feed by storage and disposal." for all products except residential use products, this sentence is required for sodium and calcium hypochlorite salts per the errata sheet for PR Notice 84-1.

[25] The language that follows "CONTAINER HANDLING" has been revised from the PR Notice 84-1 errata sheet so that it complies with the pesticide container labeling requirements in 40 CFR 156.140 – 156.159.

For Institutional/Commercial use:
STORAGE AND DISPOSAL
Do not contaminate food or feed by storage, disposal, or cleaning of equipment.
STORAGE: Keep this product dry in a tightly closed container when not in use. Store in a cool dry well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all materials before discarding this container.
PESTICIDE DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.
CONTAINER HANDLING:
[If the container is nonrefillable, use the first line ("Nonrefillable..."), the appropriate rinsing instructions for the container size and the next line ("Offer for..."). If the container is refillable, use the paragraph beginning with "Refillable container."]

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or reconditioning if appropriate or place in trash.

(For dilutable uses in containers 5 gallons or less) Clean container promptly after emptying. Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. **(For dilutable uses in containers larger than 5 gallons)** Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

Refillable container. Refill this container with pesticide [or common chemical name] only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Offer container for recycling if available or reconditioning if appropriate or place in trash."

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Label Review Manual

Chapter 14: Identification Numbers

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I. Introduction

The EPA Registration Number and the Establishment Number are required on all pesticide products. *40 CFR 156.10(a)(1)(iv)-(v)*. The purpose of an Identification Number is to provide a unique product number for regular registrations, distributor registrations, Special Local Needs registrations, and Experimental Use Permits.

II. EPA registration number

A. Purpose and Form of the Registration Number

The EPA Registration Number indicates which company holds the registration for the pesticide product, and in which sequence the product was submitted to EPA by the company. For example, the first product submission by a particular company will receive EPA file symbol -R which upon registration will become product number one; the second will be two; and so on. The registration number must be preceded by either the phrase, "EPA Registration No.", or "EPA Reg. No." *40 CFR 156.10(e)*. This phrase will be followed by a company number then a dash (-), and then the product number. Instructions for obtaining a company number are available at Chapter 14 of the Registration Manual.

B. Assignment of Registration Number

Before a pesticide product is registered under *FIFRA Section 3*, it is assigned an EPA File Symbol which is comprised of the company number followed by a series of letters representing the potential product number. Product numbers are assigned sequentially to each company. The letters are used to indicate that the product is not registered. The letters come from the word "REGULATION". Each letter represents a number starting with "1 (one)", and ending in "0 (zero)". Accordingly, R=1, E=2, G=3, U=4, L=5, A=6, T=7, I=8, O=9, and N= 0.

R	E	G	U	L	A	T	I	O	N
1	2	3	4	5	6	7	8	9	0

Therefore, if 6767-EGN were registered, it would become EPA Registration Number 6767-230. "6767" is the number identifying the company holding the registration and "230" is the number identifying that specific product.

C. Location of the Registration Number

The Registration Number must be stated on the label. Although no specific location is required, the preferred location is on the front panel near the registrant's name and address. The registration number must be set in type and style similar to and running parallel to other print on the section of the label where the registration number is located. *40 CFR 156.10 (e)*.

III. Distributor numbers

FIFRA and the regulations permit distribution or sale of a registered product under a distributor's name and address. *40 CFR 152.132*. This is called "supplemental distribution." Although distributor labels are not submitted to EPA for review or stamped accepted, questions that concern them may arise from internal or external customers. The distributor label must be the same as that for federally registered product (basic registration) except for: product name, name and address of distributor, distributor number, establishment number (final Establishment at which the product was produced), and any claims (uses, for example) that are deleted from the label. *40 CFR 152.132(d)*. No new claims may be added. Distributors may not make amendments to a product's master label. Only the basic registrant can amend the EPA-approved registered label.

Subject to the exceptions above, this regulation was intended to ensure that labeling statements made for a distributor product are *identical* to those made for the EPA-reviewed and approved basic product labeling. The Agency will however, generally permit minor formatting differences, such as different label colors and backgrounds, type styles or label sizes, provided the text, prominence and location of labeling statements on the distributor label are identical to that of the basic product and that the distributor label meets all applicable regulatory requirements.

Both a registrant's name and a distributor's name can appear on the label, but it has to be VERY clear who is doing what. (see *Chapter 15, Company Name and Address*).

Distributor products must bear the EPA Registration Number of the basic product, followed by a dash [-], and then followed by the distributor's company number. *40 CFR 152.132(d)(3)*. For example, Company A has a registered product, Kill It Dead Herbicide, EPA Registration No. 262-598. Company A enters into a supplemental distribution agreement with Company B as a distributor. The Agency receives the necessary documentation substantiating this supplemental distributor arrangement and then assigns to Company B the Number 10007. The herbicide marketed by Company B (under their product name, Make It Brown Herbicide) must bear the EPA Registration No. 262-598-10007. An EPA Registration Number consisting of three sets of numbers partitioned by dashes can readily be identified as a distributor product. As discussed above, only Company A could amend the EPA-approved registered label.

IV. EPA Establishment Number

The Establishment Number is assigned by EPA Regional Offices (domestic establishments) and the *Office of Enforcement and Compliance Assurance (OECA)* (foreign establishments). See *40 CFR 167*. A facility that produces pesticides must have a company number assigned by the Office of Pesticide Programs before an EPA Establishment Number is assigned. The Establishment Number is not reviewed by the Product Management teams. The PM teams only responsibility is to ensure that the number is formatted correctly.

A. Purpose and Location of Establishment Number

The Establishment Number indicates the final establishment at which the product was produced. *40 CFR 156.10(f)*; see also *40 CFR 167.3*. This number must be preceded by the phrase, "EPA Est.," and may appear anywhere on the pesticide product label or the immediate container but it must appear on the outer container or wrapper of the product if the establishment registration number cannot be clearly read through the outer container or wrapper. *40 CFR 156.10(f)*. It often is grouped together with the EPA Registration Number but is not required to be. [Note: The Establishment Number may be changed by non-notification. (See *PR Notice 98-10*.) The final establishment where the product will be produced might not be known when the draft label is submitted, or the registrant may intend to place the Establishment Number directly on the container rather than the label, so the Establishment Number might not appear on the draft label submitted for review.

B. State Designation

As a matter of Agency practice, letters such as MO, AZ, or PA appear after the producer's company number in establishment numbers. These letters represent the state in which the product was produced.

> ***Example 1:*** an establishment number may be written as EPA Est. (Company No.)-MO-1, which would indicate that the product was produced in the first establishment registered by that company in Missouri.
>
> ***Example 2:*** If corporation XYZ's company number is 98989, and the last phase of pesticide production takes place at producing Establishment Number 002 in Hawaii, then the Establishment Number for this product would read EPA Est. 98989-HI-002.

C. Multiple Establishment Numbers

Some registrants may produce an identical product in more than one establishment. The Agency permits the use of multiple establishment numbers on products on a case-by-case basis provided that the registrants meet existing labeling requirements and follow the format for multiple establishment numbers.

Note: A company number must be in place first, then the establishment number may be set up to reflect both the state in which the establishment is registered and also, which number it is in the state itself.

If a producer lists multiple establishment numbers, the establishment number for the actual production site of a particular product must be very obviously marked or highlighted, for example, with an arrow, a notch, a bullet, etc. For instance, a master label may list three establishments in two states, all of which produce the same product. The same label can be used at all three establishments by marking the site where individually labeled products are actually produced.

Products may also be produced in sequential steps at multiple establishments. Use of the word "last" implies that a product traveled through sequential establishments during its production. Only the establishment number of the last establishment at which a product is produced is required to be on the label. *40 CFR 156.10(f)*. If the product is changed as it moves from site to site, the required label would change at each site so that the establishment number of the final establishment up to that point is indicated on the product label at each site.

D. Foreign Establishment Numbers

Foreign producers of pesticides or devices must also have company and establishment numbers. Instructions for obtaining these numbers are included along with general guidance on company and establishment numbers provided in chapter 14 of the Agency's registration manual.

V. Special Local Need (SLN) registration number

The Special Local Need registration number (SLN number) is also known as a FIFRA Section 24(c) Registration Number. *40 CFR 162.153(e)*. These registrations are issued by the states to meet special local needs. See *40 CFR Part 162*. The number is written as "EPA SLN No." followed by the two letter state designation, then the last two digits of the year of issuance, and finally a four digit number which is the consecutive number of registrations that the registering state has issued in that particular year.

For example: If the company ABC applied for a section 24(c) registration in the State of North Carolina and it was the 34th SLN registration accepted by North Carolina in the year 1995, then the 24(c) registration number would be EPA SLN No. NC950034.

The EPA 24(c) registration number is assigned by the state and entered on the Application for Notification of State Registration of a Pesticide To Meet a Special Local Need (EPA form 8570-25).

VI. Experimental Use Permit number

A person may apply for an Experimental Use Permit (EUP) under *Section 5 of FIFRA* to develop data on either a new product or a new use site for a future FIFRA Section 3 registration. EUP applications (*EPA form 8570-17*) are assigned file symbols, which are written as Company Number-EUP-File Symbol. The file symbol is translated to an EUP registration number once the EUP has been issued by the Agency and/or an associated temporary tolerance has been established.

Note: The application for a permit may be denied. See *Section II.B* for information on the translation of file symbols to registration numbers (See *40 CFR 172.6 (a)(2)*)

For example: Company MNO, whose company number is 98979, applies for an EUP to collect data on the crop kale and no tolerance is yet established for kale. It is given a file symbol RLE until the EUP has been issued and the temporary tolerance has been established, if applicable. If this EUP application is issued, the file symbol 98979-EUP-RLE will become EUP Number 98979-EUP-152, indicating this is the 152nd permit for which this company has applied.

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Label Review Manual

Chapter 15: Company Name and Address

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Table of Contents

What's changed in this version?

- Added *Table of Contents.*
- Added *What's changed in this version?* section.
- Updated hyperlinks.
- Reformatted text to improve readability.
- Removed *Foreign registrants* section containing non-label related address requirement.
- Added company address guidance for foreign registrants under new *Using the correct name and address* section.
- Updated NPIC contact information including new hours of operation.
- Removed *Company name and address changes* section containing non-label related instructions to registrants for submitting change requests.

I. Introduction

Pesticide product labels must include the name and address of the producer, registrant, or person for whom the product was produced. 40 CFR 156.10(a)(1)(ii). For the purposes of this Chapter, this entity is presumed to be a "company" instead of an individual person.

II. Location and size

The name and address must be clearly legible in 6-point or larger type size and prominently displayed on the label. 40 CFR 156.10(a)(2). The name and address may be placed anywhere on the label; however, the front panel is preferred.

III. Using qualifiers

An unqualified name and address given on the label is considered to be the name and address of the producer.

A. Non-producer

If the name and address given is not the same as the producer's, then it must be qualified by appropriate wording such as "Manufactured for" or "Produced for." 40 CFR 156.10(c).

B. Supplemental distributor

Supplemental distribution allows a registrant to distribute or sell his/her registered product as a "distributor product" under a different name and address. The name and address of the distributor may be given on the distributor product's label instead of the registrant's, qualified by phrases such as "Packed for," "Distributed by," or "Sold by." 40 CFR 152.132(d)(2).

IV. Using the correct name and address

The name and address on the label provides a point of contact for the product. The name and address on the label should match the Agency's records as listed under the company (or distributor) number. For non-distributor products, this is the first set of numbers of the EPA Registration Number (ex. EPA Reg. No. **1234**-567). For distributor products, this is the last set of numbers of the EPA Registration Number (ex. EPA Reg. No. 1234-567-**8910**).

Note that:

- If more than one company is given, appropriate qualifiers should be used.
- The company name cannot be abbreviated unless it is easily-recognizable as an abbreviation of its full name.
- If the company name is "a division of", "a subsidiary of", "c/o" (care of), or "dba" (d/b/a or doing business as) another company, the name(s) given on the label should match the Agency's records.
- The company address should include the street address and/or PO Box™, plus ZIP Code™ of the location where correspondence may be sent.
- An authorized, designated agent's name and address may be used instead of or in addition to the company's name and address.
- For foreign registrants, the United States address of record may be used instead of or in addition to the foreign address.

V. Non-emergency telephone number

The Agency strongly encourages that labels include a company telephone number or a toll-free hotline number that allows users to obtain additional product information. PR Notice 97-4. This is intended for non-emergency product information and is different from the emergency treatment information number (e.g. poison control) that is listed under the First Aid section.

As an option, the National Pesticide Information Center (NPIC) hotline number may be used, with the suggested statement:

> "For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Standard Time. In the event of a medical emergency, call your poison control center at 1-800-222-1222."

Note that the NPIC, formerly called the National Pesticide Telecommunications Network (NPTN), has decreased their hours of operation from 6:30 AM to 4:30 PM PST seven days a week to 8:00 AM to 12:00 PM PST Monday through Friday. However, NPIC staff will typically respond to all inquiries received through voice mail, email, or social media within one business day.

Revised August 2017

Label Review Manual

Chapter 16: Graphics and Symbols

http://commons.wikimedia.org... photo by "Daderot"

Table of Contents

What's changed in this version?

- Added *Table of Contents.*
- Added *What's changed in this version?* section.
- Updated hyperlinks and added new hyperlinks for symbol examples.
- Reformatted text and style to improve readability.
- Shortened chapter title to *Graphics and Symbols.*
- Combined previous *Other graphics and symbols which are acceptable* section into *Acceptable graphics and symbols* section.
- Combined all organic logo discussions under *Organic pesticide logos* section.

I. Introduction

Almost all graphics and symbols need Agency review, whether they are submitted as part of a label amendment or are made by notification (PR Notice 98-10, Sections II.H). There are only a limited number of graphics and symbols considered to be non-FIFRA elements that can be added by non-notification (PRN 98-10, Section IV.C).

Graphics and symbols are permitted on pesticide product labels, and cannot be false or misleading or otherwise cause the product to be misbranded. Graphics and symbols must be clear in their meaning to the reader and must not obscure or crowd required label language. Including explanatory text with the graphics and symbols, while not required, would help in preventing false and misleading labeling and misbranding. This Chapter provides guidance in determining the acceptability of graphics and symbols. (PR Notice 98-10, Sections II.H)

II. Acceptable graphics and symbols

Acceptable graphics and symbols on product labels can serve to enhance the understanding of the accompanying text. Examples of acceptable graphics and symbols include the following (PR Notice 98-10, Sections II.H):

- Diagrams of how to open product containers.
- Pictures illustrating proper pesticide use.
- Graphics which display spray patterns of nozzles and/or application patterns.
- Pictograms located near the precautionary statements that illustrate the different exposure routes (oral, inhalation, or dermal) to pesticides.
- Pictures consistent with the label text showing examples of places where the pesticide may be used (e.g., a house or an office building).
- Child hazard drowning pictogram and labeling (a picture of a child turned upside down in a bucket within the universal negation symbol - a circle with a diagonal slash through it). Historically, the Agency has stated that the pictogram cannot be accompanied by the word "WARNING" as it may be confused with the human hazard signal word for the pesticide product. To avoid such confusion, the Agency generally recommends that registrants use the word "Precaution" or "Notice." However, the Agency understands that often pesticide producers purchase buckets that already have the drowning hazard pictogram and the word "WARNING"

embossed or labeled on the container. If this is the case, then when labeling the bucket with FIFRA information, registrants should make every effort to separate the FIFRA information from the pictogram and associated word "WARNING" in order to avoid confusion with the human hazard signal word for the pesticide product.

- The "Mr. Yuk" symbol (a green frowning face with its tongue hanging out) on the label and/or outer container of the pesticide product. The "Mr. Yuk" symbol may be used with the skull & crossbones symbol for Toxicity Category I products used in or around the home or pool where children may be present.

- Pictures illustrating appropriate protective gear.

- Certification symbols (i.e., NSF and Kosher symbols), which must provide proof of certification.

- Hazardous Materials Identification System/National Paint & Coatings Association/National Fire Protection Association (HMIS/NPCA and NFPA) ratings systems for hazard codes.

- Use of a logo to indicate absence of chlorofluorocarbons (CFCs) in a pesticide product. The logo must use the universal negation symbol (a red circle with a diagonal red slash through it) with the statement "Contains no CFCs or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols." immediately next to the logo, and text set in at least 6-point font. PR Notice 92-2.

- Use of the GHS (Globally Harmonized System for Hazard Communication) explosives symbol and the GHS flammability symbol. These symbols can be added to the label in addition to any warning statements on the flammability or explosive characteristics of pesticide products required under 40 CFR 156.78.

- The Good Housekeeping Seal is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the Agency does not endorse the warranty message provided by this symbol.

- Department of Transportation symbols indicating the hazard and flammability of a particular pesticide product.

- The USDA Certified Biobased Product label, which must provide proof of certification. A disclaimer statement must also be placed directly under or beside the label indicating that it does not imply safety of the product.

- Barcodes and QR codes which allow for easier scanning of prices in retail stores. QR codes for the purpose of providing directions for use of the pesticide product are considered web-distributed labeling, which is discussed in Chapter 3.

III. Unacceptable graphics and symbols

Graphics and symbols are unacceptable if they violate FIFRA 12(a)(1)(F) or FIFRA 2(q)(1)(A) or the applicable regulations describing potential false and misleading statements in 40 CFR 156.10(a)(5). Examples of graphics and symbols that would generally be considered unacceptable include the following:

- A food or flower pictured on a label which bears no directions for use on that food or flower. For example, a picture of cherries generally may not appear on a label if the product is not registered for use on cherries, or a picture of roses may not appear on a label if the product is not registered for use on roses.

- Pictures of users must be consistent with personal protective equipment (PPE) requirements on the label. For example, if the label requires that the applicator wear full chemical-resistant coveralls with goggles, the label illustration cannot show a person wearing shorts and no protective eyewear.

- Picture of a pest not claimed to be controlled by the product.

- Pictures that depict the fragrance of the product (except for antimicrobial products). Non-antimicrobial products are reviewed on a case-by-case basis.

- Pictures depicting food or food contact utensils, even in some cases where food-handling area treatments are allowed on the label. Use directions generally require that food items and food contact utensils be covered or removed before the pesticide is applied.

- Pictures of persons applying pesticides in areas accessible to children, pets, and other non-target organisms when such products may only be applied in areas inaccessible to such non-target organisms.

- Pictures of children, unless the product is registered for use on children or the product is registered for use in swimming pools. Reviewed on a case-by-case basis.
- Pictures of candy. Similarly, containers that look like food or candy are prohibited.
- Symbols implying safety or non-toxicity, such as the caduceus or rod of Asclepius symbols for medicine.
- Pictures of residential use sites when the label limits use of the product to commercial or industrial sites.
- Recycling symbol or any other symbol implying that the product and/or its container can be recycled if in fact it cannot be.
- EPA or any other agency logo which implies endorsement by a government agency.

IV. Organic pesticide logos

As discussed in Chapter 12, if the criteria described in PR Notice 2003-1 are met, a pesticide product may bear the following phrases in logo format:

"For Organic Production"

"For Organic Gardening"

"For Organic Lawn Care"

"For Use in Organic Production"

Logos from other groups that review materials proposed for organic agriculture may also be considered, e.g., Organic Materials Review Institute (OMRI). However, the following example would generally be considered unacceptable:

- Symbols which contain the words "Slow Release Nitrogen" and "Organic" are not permitted if the prominence of the symbol, large type size of the word "organic" and its position relative to the words "Slow Release Nitrogen" make it unclear whether the word "organic" refers to the fertilizer component or to the entire product.

Label reviewers should consult with the National Organic Program liaison in the Biopesticides and Pollution Prevention Division before approving any organic statements, logos, or claims.

Revised February 2018

Label Review Manual

Chapter 17: Net Contents/Net Weight

http://commons.wikimedia.org, photo by "Daderot"

Table of Contents

What's changed in this version?

- Added *Table of Contents.*
- Added *What's changed in this version?* section.
- Updated hyperlinks.
- Editorial changes to text to improve readability.
- Switched order of Section III and IV.
- Updated Introduction section to include note on declaring net contents information on application form 8570-1, and leaving net contents information blank on draft label for refillable containers.
- Updated NIST Handbook 130 reference for Bag on Valve unit measurements.

I. Introduction

The Net Contents/Net Weight statement indicates the quantity/volume of pesticide product that is in the container and must appear on the pesticide label pursuant to FIFRA12(a)(1)(E)) and 40 CFR 156.10(a)(1)(iii). Usually, draft labels include the phrase "Net Weight:" or "Net Contents:" as a means of identifying where the statement will actually appear on the final printed label. 40 CFR 156.10(d) describes how the net contents must appear on the label, but does not require the term/heading "Net Weight" or "Net Contents" to be stated on the label. However, the Agency strongly recommends that labels include one of these qualifiers for clarity, as 40 CFR 156.10(d)(1) requires that the quantity listed describe the amount of pesticide product in the container as opposed to the total weight of the pesticide product plus the weight of the container. The amount of product may be left blank on the master label in instances where more than one size of packaging is offered; however, the applicant should declare the various net contents offered in Section III of the Application for Pesticide, Form 8570-1. Additionally, the net contents may be left blank for products distributed in refillable containers. 40 CFR 156.10(d)(7).

II. Location of the statement

There is no required location for the Net Contents/Net Weight statement. The preferred location is at the bottom of the front panel below the company name and address. If the draft label under review shows the Net Contents/Net Weight statement in some other location, the reviewer may request that the statement be placed at the bottom of the front panel. The Net Contents/Net Weight quantity must be exclusive of any wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity. 40 CFR 156.10(d)(1).

III. Expression of the statement

Labels must meet the following requirements:

A. Units of measure

Conventional U.S. standard (also known as avoirdupois or imperial) units of measurement must be used on pesticide labels. Pesticide labels may also declare net contents in metric units (liters, kilograms, etc.), as long as U.S. units of measurement are declared (e.g., "Net Contents: 1 gallon (3.785 liters)"). It is not acceptable to declare net contents only in metric units. For consistency, EPA requests that applicants treat Directions for Use the same way. For example, in addition to expressing the application rate(s) in U.S. units of pound per acre, the registrant may also express the rates in equivalent metric units as kilograms per hectare.

B. Expression of net contents

The Net Contents must be stated in terms of the largest suitable units. For example, for a package containing 26 ounces of pesticide product, the label must state: "Net Contents: 1 pound (lb.) 10 ounces" rather than "Net Contents: 26 ounces." The label may indicate the net weight and quantity of individual units within the carton (e.g., "Net Weight 6.25 lbs. (20 – 5 oz. packets)"). 40 CFR 156.10(d)(4).

C. Consistency with Directions for Use

The Directions for Use on the label should not require a quantity of pesticide product that exceeds the net contents/net weight of the package, as this may mislead consumers as to the net contents or net weight in the package or the proper application of the product. An example would be a granular product stating "Net Contents: 1 pound," that requires an application rate of 5 pounds per acre.

IV. Types of products/measurement

The Net Contents/Net Weight statement shall be expressed based on the product type as follows:

- **Dry formulations** (e.g., solids, dusts, granules, pelleted or tableted baits, wettable powder, microencapsulated, and impregnated materials)
  The net contents statement must be expressed as avoirdupois pounds and ounces. 40 CFR 156.10(d)(3).

- **Liquid formulations** (e.g., soluble and flowable concentrates, ready-to-use sprays)

  The net contents must be expressed in terms of liquid measure at 68 ^{o}F (20 ^{o}C) in standard American units (gallons, quarts, pints, or fluid ounces).
  40 CFR 156.10(d)(2).

- **Pressurized products** (e.g., gases and aerosols)

  The net contents must be expressed as avoirdupois pounds and ounces.
  40 CFR 156.10(d)(3).

- **Antimicrobial wipes, insect repellent wipes, and towelettes**

  The net contents per container for wipes and towelettes (wet or dry) must be expressed as avoirdupois pounds and ounces. 40 CFR 156.10(d)(3). This requirement is imposed for the total contents of the overall container and not on the basis of each individually-

packaged wipe or towelette within the container. The net content statement is to be expressed taking into account the weight of the wipe material plus the weight of the pesticide added to the wipe, keeping in mind that the net content statement does not include the wrappers for individually-packaged wipes and towelettes. However, the net content declaration on the container may also include a statement such as *"Contains X count of x inch by y inch pre-moistened wipes."* in addition to the avoirdupois unit.

- **Bag on Valve (BOV)**

  Where a pesticide product container uses "Bag on Valve" (BOV) technology, the pesticide is contained within a bag, which is contained within a canister. In order to dispense the pesticide, pressurized gas is released within the canister, but outside of the bag. This squeezes the bag containing the pesticide, causing the pesticide to be expelled. The gas remains entirely within the canister, and the pesticide never comes into contact with the gas.

  The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) publishes "Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality," otherwise known as "NIST Handbook 130." The 2018 edition of NIST Handbook 130 requires that packages using BOV technology disclose the net quantity of the commodity in terms of weight that will be expelled from the container, enforceable after January 1, 2018. See NIST Handbook 130 (2018), Uniform Packaging and Labeling Regulation, Section 10.3, including Note.

  In the interest of consistency with the NIST regulations, the net content statement for pesticide products using BOV technology should be in terms of weight expressed as avoirdupois pounds and ounces, per 40 CFR 156.10(d)(3).

Label Review Manual: Revised September 2013

Chapter 18: Unique Product Labeling

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Elizabeth A. Sellers

I. Introduction

Certain specialty products pose a challenge to meeting the regulatory labeling requirements. Package size, shape, and composition often dictate unorthodox approaches to attaching the necessary information. While many labeling provisions of *40 CFR 156.10* are mandatory, other provisions provide the flexibility necessary to address challenging specialty products. The following examples have been accepted by the Agency and may be used as models for new and novel products that may be developed in the future. Label reviewers must address each product on a case-by-case basis, and determine whether the labeling meets applicable legal requirements.

II. Foreign language labeling

Foreign language text, in addition to the full English text, is permitted in part or in its entirety on the product so long as it is a true and accurate translation of the English text. (See *PR Notice 98-10*) A registrant may provide bilingual labeling on any product without notification. However, if it is submitted, the Office of Pesticide Programs (OPP) currently does not review the translation for accuracy or stamp/approve it. If the foreign text is inaccurate or goes beyond the reviewed and accepted English labeling, the Office of Enforcement and Compliance Assurance may take enforcement action. Products marketed in Puerto Rico can be labeled in English only or in English and Spanish.

. For products falling under the scope of the Worker Protection Standard, labels for products in toxicity categories I or II must include Spanish signal words and the statement below. (40 CFR 156.206 (e)). The Spanish signal word for toxicity category I products is "***PELIGRO***" and for toxicity category II products is "***AVISO***". The statement that appears on toxicity category I and II WPS products is as follows. Use of the statement and "Aviso" is optional for products in toxicity categories III and IV:

> ***"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"***

III. Soluble packets

An increasingly popular means of packaging dry pesticides is the water-soluble packet. For some chemicals, EPA has required water-soluble packaging to reduce exposure of mixer-loaders to dust, vapor, or liquid pesticides. This method of packaging, however, presents problems in labeling. Since the immediate container is the film, a strict application of the regulations would require front panel text to be printed on the film itself. Although recent technological advances have made such printing possible, most standard printing techniques and inks are not compatible

with the polyvinyl alcohol films. In order to accommodate this desirable method of packaging, the Agency has accepted other labeling approaches. See *PR Notice 94-8* for complete information.

The most widely used packaging is a tear-open foil envelope containing each soluble packet; the foil envelope bears the required labeling. This foil envelope method has the added benefit of protecting the soluble packet from moisture which could cause shelf-life problems. Another acceptable method is a muffin-pan type of package where each packet is enclosed in a depression with a tear-off top that seals each chamber. The tear-off top bears the required labeling.

A vital consideration in dealing with soluble packets is how to reduce the likelihood of the user removing unlabeled packets from labeled containers long before use and then forgetting what they are. Because laundry detergents and dry bleaches are also manufactured in soluble packets, there is the possibility that pesticides could be mistaken as these products. The Agency believes that simply packaging a quantity of unlabeled soluble packets in an outer container where they could be easily separated from the accompanying labeling does not meet the FIFRA registration standard. Each packet must either bear identifying labeling on the film itself (where feasible) or on packaging immediately enclosing that packet. *PR Notice 94-8* describes in more detail the concerns the Agency has with pesticide products containing water-soluble packaging (See *Chapter 10* for reduced Personal Protective Equipment for water-soluble packaging products subject to the Worker Protection Standard.)

IV. Multi-packs/co-packs

A. Registered Pesticide Packaged with a Non-Pesticide

A registered pesticide product, in one container, may be packaged with a non-pesticide component, such as an adjuvant, in a separate container (which is to be added to the pesticide during mixing). These two containers, combined in one package, may be sold as a single unit only if the adjuvant is referred to in the Directions for Use on the label.

The two containers are distributed and sold as a single retail unit, and together comprise the pesticide product. (See *40 CFR 152.3* and *FIFRA 2(u)* defining pesticide to include a "mixture of substances"). If the two components are bound together with a shrink-wrap sleeve or in a box, the full label of the pesticidal component must be visible through the wrapping, or the label must be duplicated and attached to, or printed on, the outermost container.

The regulation at *40 CFR 152.3* states that the "pesticide product" includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and labeling of any "non-pesticide" which is part of the package. This means that the Agency reviews and accepts or disapproves of the non-pesticide that is packaged with the pesticide. The reviewer

examines the non-pesticide labeling to determine whether it contains any language that conflicts with the pesticide label, but the reviewer does not actually stamp the non-pesticide label. An example of such a non-pesticide would be an activator (such as potassium permanganate) which accompanies a pesticide (sodium bromide). EPA reviews the labels for both products, but stamps only the accepted pesticide label, noting any problems or changes needed for the non-pesticide label.

B. Two or More Pesticides Packaged Together

Two or more pesticide products may be packaged in separate containers but sold together as a single unit. The user may be instructed on the label to tank mix the products that were packaged together just before application. (*FIFRA 2(u)*)

Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels must be duplicated and attached to the outermost container. (*40 CFR 156.10(a)(4)(i)*)

Approaches regarding the labeling for multi-packs and co-packs are dependent on the specific issues of each case. Registrants should contact the appropriate division for additional information before submitting registrations or amendments that feature multi-packs or co-packs or before deciding whether such packaging requires registration.

V. Small containers

Some containers are too small to contain all required label text. In such cases, it is permissible to have text located on accompanying pamphlets or other collateral material, all of which are considered product labeling. The Agency historically has required certain information to appear on the label of small containers:

- ingredient statement
- signal word
- skull and crossbones (when required)
- child hazard warning
- EPA Registration Number
- EPA Establishment Number
- the phrase "RESTRICTED USE PESTICIDE" (if so classified)
- a reference statement to any accompanying pamphlets.

Outer boxes, bubble packs, accordion-pleated attached labels, and plastic self-sealing envelopes containing additional labeling have been accepted.

Whatever the approach, it is important to stress that all labeling must accompany the product at point of sale, and that the immediate container must bear a statement referring the user to the location of any additional labeling which is securely affixed to the container. All of this labeling must be reviewed and accepted. Registrants are encouraged to consult with the Agency about special labeling needs.

VI. Child-attracting packaging ("Attractive Nuisance")

From time to time, registrants package pesticides in containers attractive to children. For example, bait-type pesticides for rodents and roaches have been marketed in little doll houses, fire trucks, and other toy-like dispensers or containers that look like food containers, e.g., a milk-carton shape. The Agency has not found these types of packages to be acceptable. It may be difficult for the reviewer to determine the package style when the final printed label is only a printer's proof and is not usually given a final review. The Agency can require child-resistant packaging when the toxicity criteria and use criteria are met. To ensure that packaging is acceptable the reviewer may require the applicant to submit the intended packaging before the product is registered. See *40 CFR 157.20*, et al.

VII. Child-resistant packaging

Child-Resistant Packaging (CRP) is defined as packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein in a reasonable time and that it not be difficult for normal adults to use properly. See *40 CFR 157.21(b)*.

If the pesticide is subject to CRP regulations the registrant must certify (*40 CFR 157.34*) to the Agency that the pesticide as packaged meets the standards set forth in the regulations (*40 CFR 157.32*). An example of the proper CRP certification language is found in *PR Notice 96-2*. Additionally, a registrant must maintain adequate records to substantiate the CRP certification for the life of the pesticide registration. Voluntary use of CRP requires the registrant meet the same standards as mandatory CRP.

Any changes in CRP will require an amendment of the pesticide registration (*40 CFR 152.44*) and a new CRP certification. This amendment must include its designation using the *American Society for Testing Materials (ASTM) standard D3475-06 "Standard Classification of Child-Resistant Packages"*. Agency approval is required before any packaging change can occur. CRP changes are not notifications.

A pesticide product may be exempt from the CRP requirements if it is 1) classified for restricted use, 2) if the package is of a large size (as defined in *40 CFR 157.24 (a)(2)*), 3) if the pesticide is not toxic, or 4) if an exemption is based on technical factors that preclude using the product. In the last two cases, the exemption must be approved by the Agency before the exemption can occur.

Outside of the listed exemptions above, the Agency has partially exempted products from some CRP requirements in two instances. For the following types of packaging, review the cited Federal Register notices to determine whether CRP requirements have been met:

1. Prefilled, nonrefillable ant and roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact (*67 FR 35910, May 22, 2002*).

2. Prefilled, nonrefillable termite insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact (*67 FR 35909, May 22, 2002*).

VIII . Pesticides used to treat seeds

A. Dye Requirements for Seed Treatment Pesticide Products

Under *40 CFR 153.155(a)*, any pesticide product intended for use in treating seeds must contain an EPA-approved dye. The purpose of such dye is to impart an unnatural color to the seed to signify that it has been so treated.

B. Exemptions to Dye Requirements (and related label statements)

However, the dye requirement does not apply if appropriate tolerances or other clearances have been established under the FFDCA for residues of the pesticide. In addition there are some exemptions from the requirement to use a dye that relate to how the product is labeled.

These exemptions are: (1) products intended and labeled for use solely by commercial seed treaters (provided a label condition is met, discussed further below); (2) products intended and labeled for use solely as at-planting or hopper box treatments; and (3) products that are gaseous in form or are used as fumigants. *40 CFR 153.155(b)(1)-(3)*.

1. **Commercial Seed Treaters.** Pesticide products intended and labeled for use solely by commercial seed treaters that do not have a tolerance or tolerance exemption need not contain a dye, "*provided* that the (pesticide product) label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process." *40 CFR 153.155(b)(1)*. An appropriate label statement would be, for example:

   "Note: This product does not contain dye and is not covered by an appropriate tolerance, tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act. To comply with 40 CFR 153.155, therefore, all seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for man or feed for animals".

   Any seed treated by a commercial seed treater using a pesticide product labeled in this manner cannot be used for or mixed with food or animal feed, or processed for oil.

   If the directions for use indicate a specific dye to use, verify that it is EPA-approved by reviewing the lists offered in *40 CFR 153.155(c)*. EPA-approved dyes for seed treatment are listed in various sections of EPA's FIFRA regulations. For instance, 40 CFR sections *180.910, 180.920*, and *180.950* contain those dyes approved for seed treatment use where a tolerance exemption has been established for the dye. In the future, *40 CFR 180.2010* will contain those dyes approved for seed treatment use where EPA has determined that residues of the dye only will be present, if at all, at levels that are below the threshold of regulation. Finally, *40 CFR 180.2020* contains those dyes approved for seed-treatment use where EPA has determined that no tolerance or tolerance exemption is needed for the dye because the use is not likely to result in residues in or on food or feed.

   To the extent that the pesticide product is covered by an appropriate tolerance, tolerance exemption or other clearance under the FFDCA, no such label statement is necessary on the pesticide product, the commercial seed treater is not required to add a dye to the pesticide product before treating seed, and the treated seed can be used for or mixed with food or animal feed, or processed for oil, in accordance with the applicable tolerance, tolerance exemption, or other clearance under the FFDCA. See *40 CFR 153.155(a)*.

Note: If a commercial seed treatment product contains no dye and no instructions to dye seeds are mentioned on the label, the label reviewer needs to ensure that the tolerance or tolerance exemptions are adequate for all ingredients in the pesticide as one would do for a pesticide with food- or feed-site uses.

2. **At-planting or Hopper Box Treatments.** If the product is intended for direct use on seed at planting time, and the pesticide is not cleared by EPA for food and feed use, the following statement is recommended on the pesticide product label:

   "Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting".

   A statement may be required to ensure no unreasonable adverse effects depending upon the characteristics of the ingredients of the product, such as:

   "Do not store excess treated seeds beyond planting time".

C. Label Statements Based on the Worker Protection Standard (WPS)

Seed treatment products may fall under the scope of the WPS depending on the type of treatment. Seed treatment on agricultural establishments in hopper-box, planter box, or other seed-treatment applications at or immediately before planting is within the scope of the WPS. Commercial treatment of seeds is not within the scope of the WPS.

An exclusionary statement may be added to a seed-treatment pesticide's label to clearly distinguish between products with uses subject to WPS and those without. The following statement may be appropriate for the labels of seed-treatment pesticide products solely used at commercial seed treatment facilities.

"Not for use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting".

Non-commercial seed treatment products must contain all required WPS labeling as appropriate. See *40 CFR 156.200*, et al. For seed treatment products, there may be a WPS exception statement that specifically applies to the Restricted Entry Interval (REI). If the treated seeds are soil injected or soil incorporated, the registrant may add the following statement directly after the REI statement in the Agricultural Use Requirements box. *PR Notice 93-7*, page 39.

"Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated".

D. Label Statements Based on Risk Assessments

The label reviewer needs to consult the risk assessment. Necessary mitigation measures may require that commercial seed treaters add information to the labeling for the seeds. Such additional language would be found in the Directions for Use instructing the seed treater to appropriately label the seeds he or she treats. To help promote proper use of the product

through its life cycle, including after it has been incorporated in the seed, any restriction on the pesticide product that relates to use of the crop or seed should be included on the seed label. Without these restrictions being transferred to the seed label, the person who buys the seed may be unaware of these restrictions. The seed label should include statements such as grazing restrictions, and replanting dates need to cover treated seed to prevent harm to birds, etc., as specified in the risk assessment.

Examples of additional label statements that may be required on seed-treatment product labels on a case-by-case basis in the risk assessment include:

"The U.S. Environmental Protection Agency requires the following statements (or a subset of the following statements as appropriate) on containers containing seed treated with (insert name of product)":

- *"Store treated seed away from food and feedstuffs".*
- *"Do not allow children, pets or livestock to have access to treated seeds".*
- *"Wear long pants, long-sleeved shirt and protective gloves when handling treated seed".*
- *"Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends)".*
- *"Dispose of all excess treated seed by burying seed away from bodies of water".*
- *"Dispose of seed packaging or containers in accordance with local requirements".*

In addition, other label statements may be required according to the risk assessment on a case-by-case basis to address identified environmental or toxicity hazards from the treated seed. Consult *Chapter 8* for detailed guidance concerning environmental hazard statements.

E. Labeling Statements Associated with Federal Seed Act

Commercial seed labels for treated seeds, as distinct from seed treatment pesticide product labels, are required to comply with both the Federal Seed Act (FSA) and USDA's regulations concerning the labeling of treated seed (as found in the *Federal Seed Act* and *7 CFR Part 201*). In addition, EPA recommends that the labeling of a pesticide product intended for use as a seed treatment also identify all the language that will be required for the seed label (under the FSA and the USDA regulations). Although the statements below are not required under FIFRA for pesticide labeling, it is considered a prudent measure to include these statements on seed-treatment pesticides so the user is aware of his or her obligations under the FSA when labeling seed.

1. **Toxicity Category I Pesticide Label Statements.** For commercial seed treatment products assigned Toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the following labeling statements are recommended to be placed in the direction for use section of the pesticide labeling to address the *Federal Seed Act* requirements for treated seed (consult: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3317429* for a detailed explanation):

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information:

   (a) a statement such as "*Poison*", "*Poison treated*", or "*Treated with Poison*",

   (b) the skull and crossbones symbol,

   (c) "*This seed has been treated with (insert name of active ingredient of pesticide)*". and,

   (d) *"Do not use for food, feed or oil purposes".*

2. **Other Commercial Seed Treatment Statements.** The following labeling statement is recommended to be placed in the directions for use section of the labeling for commercial seed treatment pesticide products that do not have appropriate tolerances or tolerance exemptions:

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with (insert name of active ingredient of pesticide). Do not use for food, feed or oil purposes".

F. Rinsing Instructions

General labeling requirements for residue removal or rinsing instructions are contained in 40 CFR 156.144 – 156. Part 156.144 (e) states that EPA may, at its own discretion or based on data submitted by any person, modify or waive the requirements of those sections or permit or require alternative labeling statements. The language below has been approved by EPA as modifications to rinsing instructions that are appropriate for labeling of seed treatment products.

1. Nonrefillable container

Plastic containers: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer container for recycling if available, reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Triple rinse as follows: *For containers with capacity equal to or less than 5 gallons*: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after

the flow begins to drip. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume - and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

For containers with capacities greater than 5 gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

2. **Refillable container**

Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents into application equipment or mix tank. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume. Replace and tighten closure. Agitate vigorously or recirculate the rinsate with a pump for at least 2 minutes, ensuring that the rinsate rinses the walls of the container. Empty the rinsate into application equipment or rinsate collection system, for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

Recycling: Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll free) or *www.acrecycle.org*.

IX. North American Free Trade Agreement (NAFTA) labeling

Registrants may volunteer products for NAFTA label development at any time.

A. Applying for Registration

The registrant should review the information provided in the "*Guidance on How to Develop a NAFTA Label*". Ultimately, a joint submission of the proposed label and the U.S. and Canadian product specifications must be made to EPA and Canada's Pest Management

Regulatory Agency (PMRA). In the United States, the submission should be as a label amendment. However, because EPA and PMRA continue to develop this process and refinethe guidance for NAFTA label development, the first step should be to contact either EPA or PMRA to obtain the most current information and to discuss the submission. Currently, Mexico has not been involved in the NAFTA labeling process, but may be in the future.

B. Registration of NAFTA Labels

For existing registrations, the U.S. and Canadian label review will run essentially independently, with each regulatory authority having independent responsibility for the booklets for use in the appropriate country and shared responsibility for the container label. Specifically, the container label would be reviewed by both regulatory authorities, while review of the booklets that contain the directions for use would be independent of each other.

For a new registration, the regulatory processes would run concurrently. The regulatory agencies would commit to the current accelerated timeframes for joint reviews. In the event of one country lagging behind in the registration process, and hence delaying approval of its label, the registrant could proceed with essentially the same label, absent the NAFTA language, and using only the Directions for Use for the country that is ready to proceed with registration.

C. Amendments to NAFTA Labels

The process required for registration or amendment of a NAFTA label is dependent on the format chosen for the labels. The preferred label format consists of separate U.S. and Canadian booklets with the respective directions for use. This format has the advantage of resulting in essentially independent regulatory processes for many types of label amendments. This approach is advantageous for registrants because it allows many types of label amendments to move ahead at the pace they normally would, without necessitating delay, repackaging, or other issues that are inherent in a single label approach.

There are several types of potential registration amendments. For the purpose of the NAFTA label, they are divided as follows:

1. **Registration amendments limited to changes that are exclusive to the country-specific booklets that contain directions for use,** (e.g., addition of a pest, change to pre-harvest interval, application timing, etc.) and that do not affect the container label. The U.S. and Canadian processes would run essentially independently of each other, with each regulatory authority taking responsibility for the content exclusive to the appropriate country-specific booklet. The container label would be reviewed as part of the amendment (since it forms part of the NAFTA label for each country). If no changes to the container label are made, the label amendment may be approved by the country involved with the booklet change. If a change to the booklet would require changes to

the container label, these changes to the container label would be provided immediately to both Agencies for their simultaneous review.

2. **Registration amendments affecting the container label** (e.g., product name change, change to precautionary statements, etc.) **that may or may not affect the booklet(s).** This type of amendment would require review by both countries. If the registrant desires to have the regulatory processes run concurrently, the regulatory agencies would be bound by their respective timeframes for the amendment, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

3. **Amendment to change the product formulation.** This may or may not directly affect the NAFTA label but could have implications for the determination that the products are substantially similar.

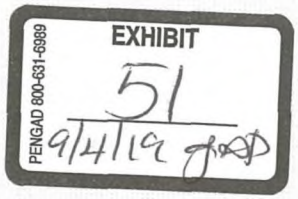
   The registration of a NAFTA label for a product is based on the product formulation being substantially similar in both countries and manufactured by the same registrant. Any application to amend the formulation would be required to be made to both agencies simultaneously to ensure that substantial similarity is maintained. The regulatory processes would run concurrently and would require review by both countries (the review may or may not include a review of the product label). The agencies would be bound by their respective timeframes for the action, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

X. Other types of labeling

Manuals

If the master label makes reference to a manual, then the registrant is required to submit it to the Agency for our review. The manual should describe in detail any special procedures and/ or technical apparatus involved in the application of the product.If the manual is inconsistent with the EPA approved label, the Agency will consider the product misbranded.

Docket Number EPA-HQ-OPP-2009-0361
www.regulations.gov



Glyphosate

Proposed Interim Registration Review Decision
Case Number 0178

April 2019

Approved by: _____

Charles "Billy" Smith
Acting Director
Pesticide Re-evaluation Division

Date: 4/23/19

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) *Proposed Interim Registration Review Decision* (PID) for glyphosate acid and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, 103613, and 417300, case 0178), and is being issued pursuant to 40 CFR § 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an Interim Registration Review decision before completing registration review. Among other things, the Interim Registration Review Decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review case. Additional information on glyphosate can be found in the EPA's public docket (EPA-HQ-OPP-2009-0361) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided as http://www2.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing a PID for glyphosate so that it can (1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation (see Appendices A, B, and C). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the Services) to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the EPA has not yet fully evaluated risks to listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for glyphosate prior to completing the glyphosate's registration review. Likewise, the agency will complete endocrine screening for glyphosate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. Last, the EPA will determine whether pollinator exposure and effects data are necessary to make a final registration review decision for glyphosate and issue a data call-in (DCI) to obtain any such data prior to completing the glyphosate registration review case. See Appendices D and E, respectively, for additional information on the listed species assessment and the endocrine screening for the glyphosate's registration review.

The glyphosate registration review case covers glyphosate acid (PC code 417300) and the following salt forms with active pesticide registrations: isopropylamine salt (pc code 103601), ammonium salt (PC code 103604), ethanol amine salt (PC code 103605), diammonium salt (PC code 103607), dimethyl ammonium salt (PC code 103608), and the potassium salt (PC code 103613). Glyphosate is a non-selective, systemic herbicide registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, cereal grains, and other field crops. Non-agricultural uses include residential spot treatments, aquatic areas, forests, rights of ways, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate is also registered for use on glyphosate-resistant crops such as alfalfa, corn, soybean, cotton, canola, and sugar beets. The first pesticide product containing glyphosate was registered in 1974; a Reregistration Eligibility Decision (RED) for glyphosate was completed in 1993. Since then, the EPA has reviewed the risk assessments for glyphosate to determine if updates were necessary when new uses were added to glyphosate labels.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why glyphosate is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA's proposed interim registration review decision; and, last, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Glyphosate's Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for glyphosate with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of glyphosate.

- July 2009 - The *Glyphosate Preliminary Work Plan (PWP)*, Human Health Scoping Document, and Environmental Fate and Effects Problem Formulation were posted to the docket for a 60-day public comment period.

- December 2009 - The *Glyphosate Final Work Plan (FWP)* was issued. Comments received on the PWP covered the following topics: opposition to the use of glyphosate, the toxicity of glyphosate formulations and inert ingredients, use and usage trends, human health risks, ecological risks, endocrine disruption, and the benefits of glyphosate. The public comments received did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- September 2010 - A Generic Data Call-In (GDCI) for glyphosate was issued for data needed to conduct the registration review risk assessments. All required data were

submitted and reviewed. The registration review GDCI for glyphosate is considered satisfied.

- December 2016 – The agency convened a FIFRA Scientific Advisory Panel meeting to consider and review a set of scientific issues related to the EPA's evaluation of the carcinogenic potential of glyphosate. The meeting agenda, the agency's cancer issue paper, charge questions for the panel, transcript, and final report are available on EPA's website: https://www.epa.gov/sap/meeting-materials-december-13-16-2016-scientific-advisory-panel. Additional supporting materials and comments received from the public can be found in docket EPA-HQ-OPP-2016-0385 at www.regulations.gov.

- December 2017 – The agency published the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (dated December 12, 2017), the *Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate* (dated December 12, 2017), the *Glyphosate Draft Human Health Risk Assessment for Registration Review* (dated December 12, 2017), the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* (dated September 8, 2015) online (https://www.epa.gov/ingredients-used-pesticide-products/draft-human-health-and-ecological-risk-assessments-glyphosate).

- February 2018 - The agency announced the availability of the human health and ecological risk assessments for a 60-day public comment period. Over 238,000 comments were received during the comment period, most of which came from various mass mail campaigns. Approximately 2,244 unique submissions were received from various stakeholders, including pesticide registrants, industry groups, farmers, grower groups, private citizens, non-governmental organizations, states, and the US Department of Agriculture (USDA). These comments and the agency's responses are summarized below. The comments did not change the risk assessments or registration review timeline for glyphosate.

- September 2018 – The Environmental Working Group, joined by Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farm, Inc. summitted a petition to the agency. The petition requested that the EPA lower the tolerance for oats and explicitly prohibit preharvest use on oats on glyphosate US labels. The agency is still reviewing this petition and has issued a Federal Register Notice of Filing for public comment in docket EPA-HQ-OPP-2019-0066. The agency intends to respond to this petition concurrently with the issuance of the *Interim Registration Review Decision* for glyphosate.

- March 2019 - The agency is now announcing the availability of the *Proposed Interim Registration Review Decision* (PID) in the docket for glyphosate, for a 60-day public comment period. Along with the PID, the following documents are also posted to the glyphosate docket:

- *Glyphosate: Response to Comments, Usage, and Benefits* (dated April 18, 2018)
- *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (dated April 23, 2019)
- *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate* (dated November 21, 2018)

B. Updates Since the Issuance of the Glyphosate Risk Assessments

The Agency received on September 27, 2018 a petition from the Environmental Working Group, Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farms, Inc. The petitioners request that the agency reduce the tolerance of the pesticide glyphosate in or on oats from 30 ppm to 0.1 ppm and modify labels to explicitly prohibit preharvest use on oats. The petitioners assert that the current tolerance level for oat is not protective enough when taking into consideration the actual dietary exposure to glyphosate in oats and the potential carcinogenicity of glyphosate. The agency is still reviewing this petition. Since this petition was submitted outside of the public comment period for the human health and ecological risk assessments, which closed on April 30, 2018, EPA has not considered it as a public comment on the risk assessments in preparation of this Proposed Interim Registration Review Decision. However, the Agency will treat this petition as a public comment on this Proposed Interim Registration Review Decision; a copy of the petition will be posted to the glyphosate registration review docket. The EPA intends to address this petition concurrently with the development of the Interim Registration Review Decision for glyphosate, taking into consideration issues raised in the petition and any comments the agency receives on its Notice of Filing.

In accordance with FFDCA section 408(d)(3), EPA is publishing EWG's petition for public comment; the public comment period will close 30 days after publication. The full petition is posted in docket EPA-HQ-OPP-2019-0066 at www.regulations.gov. This Proposed Interim Decision reflects the conclusions of EPA's most recent risk assessments and does not address the claims raised in the petition.

C. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the glyphosate preliminary risk assessments, which opened on February 27, 2018 and closed on April 30, 2018, the agency received 238,290 comments. Approximately 2,244 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, and the US Department of Agriculture. Most comments came from mass mail campaigns, and approximately 200 substantive comments were received from various stakeholders. Comments relating to widespread concerns, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below. Due to the high volume of comments received for glyphosate, the agency has combined comments by topic instead of responding to individual stakeholders and has focused its responses on comments that have not been addressed previously via the FIFRA SAP meeting or in previous registration

review documents for glyphosate. The comments did not result in changes to the agency's risk assessments. The agency thanks all commenters for their comments and has considered them in developing this PID.

For more detailed responses to comments relating to the human health risk assessment, see the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment*. For more detailed responses to comments relating to the ecological risk assessment, see the *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate*. For detailed responses to comments on the use/usage of glyphosate and the benefits, see the *Glyphosate: Response to Comments, Usage, and Benefits*. All responses to comments documents are available in the public docket for glyphosate.

Comments About the EPA's Cancer Evaluation:

Many commenters expressed disagreement with the EPA's cancer conclusion, citing the International Agency for Research on Cancer's (IARC's) 2015 classification of glyphosate as "probably carcinogenic to humans." Comments were also received regarding the EPA's weight of evidence evaluation of the animal carcinogenicity data.

The EPA Response: The EPA conducted an independent evaluation of the carcinogenic potential of glyphosate and has determined that glyphosate is "not likely to be carcinogenic to humans." The agency's cancer classification is based on a thorough weight-of-evidence review of all relevant data and is in accordance with the agency's 2005 *Guidelines for Carcinogen Risk Assessment*.[1] The agency presented its draft cancer evaluation to the FIFRA Scientific Advisory Panel (SAP) in December 2016. Although the SAP did not reach consensus on several questions, none of the panelists believed that glyphosate should be classified as "likely to be carcinogenic to humans" or "carcinogenic to humans." Given the variety of opinions expressed, the agency revised its cancer evaluation and addressed comments from the SAP where consensus appeared to be reached. EPA's full weight-of-evidence evaluation can be found in the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, available in the glyphosate public docket (EPA-HQ-OPP-2009-0361).

Comments received from stakeholders concerning the weight of evidence evaluation were previously addressed in the *Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate* (also available in the glyphosate public docket).

EPA's cancer evaluation is more robust than IARC's evaluation. IARC's evaluation only considers data that have been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered a subset of the studies included in the EPA's evaluation. For instance, IARC only considered 8 animal carcinogenicity studies while the agency used 15 acceptable carcinogenicity studies in its evaluation. The EPA also excluded some studies that were not appropriate for determining the human carcinogenic potential of glyphosate, such as studies in non-mammalian species (*i.e.*, worms, fish, reptiles, and plants) which IARC used in its evaluation.

[1] https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment

The Agency's cancer evaluation for glyphosate is also more transparent. EPA's draft cancer evaluation was presented to a FIFRA SAP for external peer review. EPA solicited public comment on the carcinogenic potential of glyphosate as part of the SAP process, which is well-documented with an agenda, transcript, meeting notes, and final SAP report. EPA responded to the SAP report, addressed panel recommendations, and made revisions to its cancer assessment that were transparent and provided to the public. EPA also solicited public comment on its full human health and ecological risk assessment for glyphosate in February 2018. In contrast, IARC meetings are not accessible to the public. Its deliberations are closed, its process does not allow for public comments to be submitted for consideration, there are no materials provided in advance of the meeting, and IARC's reports are final without an external peer review.

The EPA has not identified any new information received during the public comment period which ended on April 30, 2018 that would result in changes to the conclusion of its cancer assessment. The agency's cancer conclusion is consistent with other regulatory authorities and international organizations, including the Canadian Pest Management Regulatory Agency, the Australian Pesticide and Veterinary Medicines Authority, the European Food Safety Authority, the European Chemicals Agency, the German Federal Institute for Occupational Safety and Health, the Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

Comments on the EPA's Use of Open Literature Studies:

Many commenters asserted that the EPA relies too heavily on industry-funded studies and that these studies are not accessible to the public. Commenters requested that the EPA use open literature studies to assess glyphosate and point to various open literature studies describing various human health and ecological effects.

The EPA Response: The EPA requires a substantial amount of data to be collected and submitted for pesticide registration and registration review (see 40 CFR part 158 data requirements, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration). The required data provide a wide range of information and include the following: product chemistry, product performance, studies that determine hazard to humans and domestic animals, studies that determine hazard to non-target organisms, post-application exposure studies, applicator/user exposure studies, pesticide spray drift studies, environmental fate, and residue chemistry studies. Although many of these studies are submitted by pesticide producers, the EPA has rigorous guidelines for how studies should be conducted (https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic). The agency independently evaluates required studies for scientific acceptability. Laboratories conducting studies must address Good Laboratory Practices (GLP) designed to ensure data quality and integrity. The EPA's Office of Enforcement and Compliance Assurance (OECA) periodically inspects labs that conduct required studies to ensure that labs are in compliance with GLP regulations.

When studies are submitted to the agency for review, test reports must summarize and supply all the individual data obtained as part of the study. An independent evaluation is prepared for each study and a Data Evaluation Record (DER) is generated to summarize the study methods, results, and conclusions. DERs are subject to an internal peer review process and scientific review

committees within the Office of Pesticide Programs to ensure accuracy and consistency of interpretation prior to finalization.

Registrant-submitted studies are proprietary, and under FIFRA, cannot be released to any representative of a multinational pesticide producer or to anyone who intends to deliver such information to a multinational pesticide producer. Anyone not associated with a multinational pesticide producer may file Freedom of Information Act (FOIA) requests to access studies evaluated by the agency. For information on how to submit FOIA requests to access certain glyphosate studies, visit the EPA's website: https://www.epa.gov/foia/foia-request-process.

The EPA also reviewed the open literature to conduct both human health and ecological risk assessments.

The open literature review conducted for human health risk assessment is described in the document *Glyphosate—Systematic Review of Open Literature*. For its cancer evaluation, the EPA conducted an additional fit-for-purpose systematic review to obtain relevant and appropriate open literature studies with the potential to inform the human carcinogenic potential of glyphosate. This additional review is described in the agency's *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* which is available in the public docket. The extensive list of journal citations provided by some commenters was screened for new studies not previously considered in the EPA's search of the open literature and did not turn up any studies that would impact the conclusions the EPA reached in its human health risk assessment.

The open literature data evaluated for ecological risk assessment is described in the agency's *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts* and also in *Appendix G Bibliography of Ecotox Papers*. The extensive list of journal citations provided by some commenters was screened for potential new information relevant to the ecological risk assessment. The information submitted generally support the conclusions the EPA reached in its ecological risk assessment and do not warrant any changes.

The EPA's criteria for evaluating open literature data for both human health and ecological risk assessment are available online (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open).

Comments on Glyphosate Residues in Foods and Beverages:

Many commenters pointed to reports of glyphosate residues being detected in food/beverage commodities such as cereal, wine, orange juice, and others and express concerns about consumer safety. Others pointed to use of glyphosate as a pre-harvest desiccant for wheat as a source of glyphosate residues in cereal products.

The EPA Response: The EPA is aware of reports of glyphosate residues being detected in various foods and beverages. Due to its widespread use, trace amounts of glyphosate residues may be found in various food/beverage commodities. However, these trace amounts are below maximum residue levels established by the agency for those commodities and are not expected to pose risks of concern to consumers. For example, EPA has received results of testing of glyphosate residues in orange juice at a maximum of 26 parts per billion (ppb). At this

concentration, a 10 kg child would have to consumer approximately 385 liters of orange juice every day to reach the chronic reference dose of 1 mg/kg/day (the maximum acceptable oral dose that is the threshold of concern).

EPA evaluated dietary exposure to all population subgroups, including children, infants, and women of child-bearing age. There were no dietary risks of concern for glyphosate using an unrefined analysis, which (1) assumes that all food commodities contain maximum legal residues (*i.e.*, tolerance-level residues) and all registered food crops have been treated with glyphosate, and (2) uses high-end estimates of glyphosate in drinking water.

Commenters point to the use of glyphosate as a pre-harvest desiccant for wheat as a source of glyphosate residues in cereal products. The wheat desiccant use was considered in the agency's dietary risk assessment; EPA assumed maximum legal residues in wheat and other cereal grains. Taking exposures from those residues into consideration in its most recent human health risk assessment, EPA's estimation of risk from aggregate exposure to glyphosate, even including residues from pre-harvest desiccant use on wheat, is below the agency's level of concern. However, the agency has received a petition from the Environmental Working Group concerning the tolerance for oats and pre-harvest use on oats for which the agency is taking public comment. Additional information is described in section I.B of this document.

Comments on Formulations Toxicity:

Many commenters expressed concerns that glyphosate formulations are more toxic than glyphosate alone and questioned the toxicity of inert ingredients and the lack of transparency for inert ingredients and other contaminants in pesticide products.

The EPA Response: Most pesticide products contain substances in addition to the active ingredient (known as inert ingredients) which aid in the performance and effectiveness of the pesticide product. All active and inert ingredients must be approved by the agency when a pesticide product is first registered, including for glyphosate products. Since there are over 500 glyphosate products registered at different times in the US, the agency has assessed new inert ingredients at multiple points over the years for different formulations of glyphosate. The EPA evaluates the active and inert ingredients' hazard potential (*i.e.*, toxicity) with a battery of toxicity data. Any contaminants or impurities associated with formulation components must be reported to the agency and evaluated on a case-by-case basis. The agency reviews the amount in the formulation, the manufacturing information, and information on what steps are taken to limit or remove impurities. EPA can require that any inert ingredients of toxicological concern be listed in the ingredients statement of the label if determined to pose a hazard to humans or the environment (CFR § 156.10(g)(7)).

Glyphosate has been studied in a multitude of studies, including on multiple formulations that contain glyphosate. All studies of adequate scientific caliber that the Agency was aware of were incorporated into the risk assessment. For the glyphosate ecological risk assessment, ecotoxicity data on glyphosate formulations were reviewed in addition to data on glyphosate alone and relevant studies were summarized in the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts*.

For human health risk assessment, the EPA searched the open literature to find glyphosate formulations toxicity data but there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design. Furthermore, there are even fewer instances of studies comparing toxicity across formulations. Most studies using commercial formulations identified as part of EPA's review were *in vitro* studies, which are difficult to translate into *in vivo* effects where metabolism and clearance would play a large role in potential toxicity. EPA gave *in vivo* studies greater weight, however none of the *in vivo* studies with commercial formulations were found to be of adequate quality for use in human risk assessment. Common limitations observed in *in vivo* formulations studies include: lack of test material information, exposure conditions not adequately described/documented, data were presented only as graphs and measures of variability were not included, samples sizes were too small or not reported, only one dose was tested, age/health of study animals were not reported, and a mode of action/adverse outcome pathway was not established.

The EPA has been collaborating with the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences to develop research intended to evaluate the role of glyphosate in product formulations and the differences in formulation toxicity. The results of this research will be considered when available. Additional information on the NTP research plan for glyphosate is available online: https://ntp.niehs.nih.gov/results/areas/glyphosate/index.html.

If at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, the EPA intends to review it and determine the appropriate regulatory action.

Comments About the Monarch Butterfly:

Many commenters such as the Center for Food Safety, Center for Biological Diversity, Natural Resource Defense Council, and Beyond Pesticides expressed concerns that the EPA's risk assessment is not protective of monarch butterflies and plant resources for monarchs, such as milkweed. In general, commenters asserted that the EPA has not done enough to protect monarch butterflies when monarch populations have been in decline in recent decades. Commenters urged the EPA to restrict or ban glyphosate on the grounds that it is killing milkweed, a key resource for monarch butterfly larvae.

The EPA Response: Monarch butterfly conservation is an important issue for the agency. While herbicides like glyphosate have been implicated in the decline of the monarch butterfly population, it is not known to what extent pesticides in general may play a role. It is important to note that threats to the monarch butterfly population are multi-pronged and include loss of breeding habitat, loss of overwintering habitat in Mexico,[2] changes in weather patterns (including winter storms), disease, and other factors.[3]

[2] Vidal, O., Lopez-Garcia, J., and Rendon-Salinas, E. (2014). Trends in Deforestation and Forest Degradation after a Decade of Monitoring in the Monarch Butterfly Biosphere Reserve in Mexico. *Conservation Biology*, 28: 177-186.
[3] Agrawal, A. and Inamine, H. (2018), Mechanisms behind the monarch's decline. *Science*, 22: vol. 360, Issue 6395, pp.1294-1296.

A holistic approach is needed for monarch conservation and such an approach should consider herbicides in general as well as other factors that may play a role in the monarch decline. In addition, it is important to balance weed management needs with monarch conservation needs. To that end, the EPA published the *Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly* for public comment in 2015 (available in docket EPA-HQ-OPP-2015-0389 at www.regulations.gov). In this document, the EPA sought feedback from stakeholders on strategies for managing risks to monarch butterflies and sought specific information on factors affecting the monarch population, including information such as:

i. volume of use of various herbicides in areas critical to the monarch butterfly and where milkweed species are commonly found;
ii. information on the monarch butterfly lifecycle, seasonal distribution, its population demographics over time, and any modeling analysis relevant to critical life stage parameters;
iii. availability of laboratory or field data that specifically relates to the effects of various herbicides on the milkweed plant species;
iv. information on both spatial and temporal parameters of weed management needs particularly where herbicide use may overlap with habitat of the monarch butterfly development, reproduction, and migration; and
v. information on existing practices that promote co-occurrence of agricultural production with maintenance of milkweed populations.

Overall, the EPA received good suggestions from stakeholders on how to manage risks to monarch butterflies. Suggestions from stakeholders include the following:

i. broad stakeholder involvement, outreach, and partnering;
ii. focusing on voluntary, incentive-based, and locally-led initiatives;
iii. promotion and use of best management practices to reduce pesticide exposure;
iv. promotion and use of integrated pest management;
v. development of label language to protect the monarch butterfly;
vi. supporting milkweed habitat in non-agricultural areas;
vii. more communication, education, and outreach on the monarch butterfly;
viii. continue to better understand monarch biology and needs; and
ix. ensure that any actions taken are done in a manner that balances monarch conservation priorities with other priorities such as native and invasive weed control.

In general, the EPA has focused its monarch conservation efforts on activities that are within the purview of the Office of Pesticide Programs (OPP) and are possible to implement through OPP's registration review, registration, and stakeholder outreach activities. The EPA is focused on four main areas: label language; cooperative efforts between the EPA and other federal, state, and private partners/stakeholders; outreach and communication; promoting best management practices and integrated pest management; and science and risk assessment. In the last several years, the EPA has made progress in many of these focus areas. Major milestones achieved include the following:

- In 2017, the EPA promoted pollinator/monarch conservation activities at the state level by finalizing the *2018-2021 FIFRA Cooperative Agreement Guidance*[4] for states. The

[4] https://www.epa.gov/compliance/fiscal-year-2018-2021-fifra-cooperative-agreement-guidance

2018-2021 Cooperative Agreement Guidance was modified to include the following monarch conservation activities:

- Establish/maintain relationships with federal, state, tribal and local agencies, beekeeper organizations, grower organizations (e.g., commodity groups), crop advisors, pesticide manufacturers (registrants), and other stakeholder groups within the region to assist where needed in combined pollinator protection activities.
- Providing continuing education opportunities to keep growers, applicators, and handlers up-to-date on the most recent methods to protect pollinators (including monarchs), such as integrated pest management, best management practices, and integrated vegetation management.
- Developing and implementing managed pollinator protection plans focusing on managed bees, as well as monarch butterflies and other native pollinators.
- Work with co-regulators and stakeholders to develop measures to determine the effectiveness of these plans in reducing pesticide risk to pollinators.
- Provide technical assistance, education and outreach to support habitat restoration efforts to enhance/supplement forage for bees and other pollinators, such as the monarch butterfly.
- Promote the use of best management practices, integrated roadside vegetation management, and mowing best practices in roadsides, rights-of-ways, or managed natural areas which may support pollinator habitat and in turn support foraging honeybees, monarch butterflies, and other pollinators.

EPA regulates the registration, distribution, sale, and use of pesticides. The states have primary authority for pesticide compliance monitoring and enforcement. EPA provides funds to the states for pesticide education and outreach as well as compliance monitoring and enforcement activities under the FIFRA State and Tribal Continuing Environmental Program cooperative agreements[4]. FIFRA Cooperative Agreement Guidances, which are periodically updated, outline areas of cooperation between the EPA and the states and tribes, and describe specific pesticide program activities where grant money may be disbursed. Adding monarch conservation activities to the 2018-2021 FIFRA Cooperative Agreement Guidance empowers states to prioritize pollinator/monarch conservation activities depending on each state's needs and priorities.

- In 2017, the EPA adopted advisory environmental hazards label language for pesticide products that are toxic to plants in its Interim Registration Review Decisions to alert pesticide users of potential effects to non-target organisms: *"This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated area. Protect the forage and habitat of non-target organisms by minimizing spray drift. For further guidance and instructions on how to minimize spray drift, refer to the Spray Drift Management section of this label."*

- In 2018, the EPA organized four webinars to educate stakeholders on ways to reduce pesticide spray drift and ways to use integrated pest management principles in managing agricultural lands. The webinars are as follows:

- *Strategies for Managing Pesticide Spray Drift Webinar*, covered the fundamentals of spray drift management.[5]
- *Integrated Pest Management: Strategies for Pollinator Habitat Promotion and Conservation in Agricultural Areas*, covered integrated pest management principles for managing agricultural lands.[6]
- *Best Practices for Aerial Application*, a more in-depth look at aerial application.[6]
- *Best Practices for Ground Application*, a more in-depth look at ground application.[6]

- The EPA is continuing to collaborate with states, federal agencies, and other stakeholders in order to coordinate on conservation efforts and aid in scientific risk assessment. For example, the EPA is currently working with the Fish and Wildlife Service on the assessment of the monarch butterfly species status, and is engaged in discussions with the US Department of Agriculture, the State FIFRA Issues Research And Evaluation Group (SFIREG), and the Association of American Pesticide Control Officials (AAPCO) on various pesticide policy issues, including pollinator/monarch protection efforts.

Stakeholders are encouraged to visit the EPA's new monarch butterfly website for resources and news on the monarch front: https://www.epa.gov/pollinator-protection/protecting-monarch-butterflies-pesticides. In this proposed interim registration review decision for glyphosate, the agency is proposing risk mitigation measures to manage off-target spray drift to protect non-target organisms. Further information on the EPA's proposed interim decision and the agency's rationale is described in Section IV of this document.

Comments About Pollinators:

Several commenters, including the Pollinator Stewardship Council and Colorado State Beekeepers Association, discussed potential direct effects to honey bees and their health, particularly as it related to sublethal effects on honey bee navigation and appetite and cited various open literature references about honey bee health.

The EPA Response: The agency appreciates this additional information concerning honey bee toxicity data. There is uncertainty regarding the relationship of sublethal effects such as inhibition of navigation and loss of appetite, relative to the EPA's standard assessment endpoints (*i.e.*, impaired survival; growth; development). Additionally, the ecological assessment included discussion about a study that tested for colony-level effects (Thompson et al. 2014), which did not show that glyphosate adversely affected adult or developing young (brood). The EPA may require additional pollinator data in order to complete its evaluation of risk to bees prior to a final decision for registration review.

[5] This webinar's materials are posted online at: https://www.epa.gov/reducing-pesticide-drift/strategies-managing-pesticide-spray-drift-webinar-materials
[6] EPA is working on posting the materials for this webinar.

Comments on the Presence of Glyphosate in Surface Water:

Several commenters such as Beyond Pesticides and Friends of the Earth cited a recent report from the US Geological Survey (USGS) indicating that glyphosate had been detected in aquatic systems.

The EPA Response: The agency is aware of the recent 2014 USGS report (toxics.usgs.gov/highlights/2014-04-23-glyphosate_2014.html). The USGS monitoring data were considered as part of the EPA's ecological risk assessment (see Section 3.4 of the ecological risk assessment). The USGS data are ambient monitoring data and not targeted spatially or temporally to glyphosate use, so the extent that monitoring detections directly correlate to certain glyphosate applications is uncertain. These data have limited use for risk calculation but are useful as an additional line of evidence. The occurrence of glyphosate in some waterbodies (aside from its uses that include direct applications to certain waterbodies) is consistent with the EPA's analysis and was factored into risk assessment.

Comments Relating to Endangered Species Risk Assessment and Synergy:

The Center for Biological Diversity (CBD) submitted comments which focus on the EPA's duty to consult with the Services on the registration review of glyphosate in accordance with the Endangered Species Act (ESA). The CBD's comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the agency's preliminary determinations regarding the effects of glyphosate on listed species and their designated critical habitat for the glyphosate registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

The EPA Response: The EPA plans to address many of the concerns regarding listed species as part of the implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. See Endangered Species Assessment in Appendix D of this document for more information. The EPA will address concerns specific to glyphosate particularly with regard to pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See Endocrine Disruptor Screening Program in Appendix E of this document for more information regarding endocrine disruption. The EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. The EPA intends to release this policy for public comment. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's registration review decision for glyphosate.

Comments Relating to the EPA's Use Reports for Glyphosate:

A number of private citizens expressed concern that the EPA did not adequately assess the large volume of glyphosate use and the large number of use sites as part of registration review. Some commenters, such as Center for Food Safety, requested that the EPA update its use reports for glyphosate and provide more accurate estimates of use and usage.

The EPA Response: At various points in registration review, the EPA has provided estimates of agricultural usage for glyphosate. The following use reports were previously published in the glyphosate registration review docket: the 2008 *Screening Level Estimates of Agricultural Uses of the Case Glyphosate* and the 2015 *Updated Screening Level Usage Analysis (SLUA) Report for Glyphosate Case PC #s (103601, 103604, 103607, 103608, 103613, 417300)*. As part of this proposed interim registration review decision, the EPA is also providing updated agricultural and non-agricultural usage information, which are included in the *Glyphosate: Response to Comments, Usage, and Benefits*, also available in the public docket. A summary of all the current use sites for glyphosate along with current labeled applications rates and other application parameters are also available in the *Joint Glyphosate Task Force's Use Summary Matrix*, available in the glyphosate public docket.

Comments on Glyphosate's Connection to Resistant Weeds:

Many stakeholders (*e.g.*, Beyond Pesticides, Center for Food Safety, Center for Biological Diversity) commented on glyphosate's connection to weed resistance, stating that widespread use of glyphosate has resulted in increased weed resistance, particularly in glyphosate-resistant crops. Commenters noted that there is potential for resistance to spread between herbicide resistant crops and related plants. Other stakeholders (*e.g.*, Kansas Agribusiness Retailers Association, Almond Alliance of California, Iowa Corn Growers Association) state that glyphosate is effective on weeds that are resistant to other herbicides and is still a useful tool for growers despite weed resistance issues.

The EPA Response: Whenever a herbicide is used, there is a potential for that use to contribute to the evolution of herbicide resistance, particularly if the population of a weed species is subjected to repeated sublethal doses of herbicide. Weed resistance commonly occurs but despite resistance problems, glyphosate remains an important weed management tool. Glyphosate is still effective on many weed species that have shown resistance to other herbicides. To combat weed resistance, EPA encourages tank-mixing herbicides, rotating different mechanisms of action, crop rotation, and the use of integrated pest management programs. To maintain some of the most important benefits of glyphosate, growers must use herbicides responsibly as part of an integrated weed control strategy and be proactive in employing good weed resistance management practices.

Herbicide resistance can occur through pollen-mediated gene flow from resistant crops to weedy relatives. Additionally, glyphosate-resistant biotypes of some weeds can rapidly disperse through pollen-mediated gene flow. The United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) regulates the planting, importation, or transportation of genetically engineered plant crops under the Plant Protection Act. Most genetically engineered plants are "regulated articles" and must receive prior approval from APHIS before introduction.

Helping to educate growers on how to manage weed resistance is a top priority for the agency. The EPA is proposing to require herbicide resistance management labeling as part of this Proposed Interim Registration Review Decision (see section IV of this document). The EPA has also published two Pesticide Registration Notices (PRNs) which address pest resistance management. PRN 2017-1[7] promotes mechanism of action labeling by pesticide registrants. PRN 2017-2[8] provides specific guidance for managing herbicide resistance, including labeling, education, training, and stewardship strategies for pesticide manufacturers, producers, formulators, states, grower groups, growers, and other interested stakeholders.

Comments from Mass Mail Campaigns:

The EPA received comments from nine mass mail campaigns. Two mass mail campaigns were organized by Bayer Crop Science and an unidentified organization and included comments from farmers, agricultural professionals, and general consumers urging the EPA to keep glyphosate accessible. Seven mass mail campaigns came from the following environmental non-governmental organizations: Friends of the Earth, Center for Food Safety, Environmental Action, Pesticide Action Network, Organics Consumer Association, Center for Biological Diversity, and an unidentified organization. These seven campaigns urged the EPA to restrict glyphosate, protect the monarch butterfly, and/or reconsider its cancer conclusion.

The EPA Response: The agency has conducted comprehensive human health and ecological risk assessments for glyphosate and has not received any information from public comments that would warrant revising the conclusions of its risk assessments. The EPA did not identify any risks of concern for humans from exposure to glyphosate. In addition, the agency determined glyphosate is not likely to be carcinogenic to humans. The EPA has identified risks primarily from spray drift for non-target organisms. The agency has weighed the risks and benefits of glyphosate use as part of its proposed interim registration review decision. In general, the benefits that glyphosate confers to growers outweighs the geographically limited risks to non-target organisms. It is important to balance the needs of weed management with protections for non-target organisms and the agency is proposing risk mitigation measures to manage off-target spray drift and promote weed resistance management. Further information on the EPA's proposed interim decision and the agency's rationale is described in Section IV of this document.

Comments from USDA's Office of Pest Management Policy:

In its comments to the glyphosate registration review docket, USDA submitted information on the benefits of glyphosate, and furnished information on the non-agricultural uses of glyphosate, particularly in non-food tree crops, aquatic areas, and pasture/natural lands.

The EPA Response: The agency thanks USDA for its comments and especially appreciates the information on use of glyphosate in non-agricultural areas, as that information is not readily

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[7] *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling.* https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management

[8] *Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship.* https://www.epa.gov/pesticide-registration/prn-2017-2-guidance-herbicide-resistance-management-labeling-

available. The benefits and information on application rate, timing, and typical practices for non-agricultural uses have been considered as part of this Proposed Interim Registration Review Decision.

II. USE AND USAGE

Glyphosate is a broad-spectrum, systemic glycine herbicide which inhibits the enzyme enolypyruvyl shikimate-3-phosphate (EPSP) synthase in plants and inhibits aromatic amino acid synthesis. It is the only herbicide in the Weed Science Society of America's (WSSA) group 9 class and it has a unique mode of action. Glyphosate is formulated as ready-to-use solution, water-dispersible granules, soluble concentrate, emulsifiable concentrate, flowable concentrate, water soluble packaging, pressurized liquid, pellets/tablets, and tree injection shells. It can be applied as a pre-emergent, post-emergent, or as a pre-harvest application to the crop to treat a variety of emerged grass and broadleaf weeds. In a few crops (ex. sugarcane), glyphosate is used as a plant growth regulator.

Glyphosate is registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, legumes, cereal grains, and other field crops. Glyphosate is also registered for use on glyphosate-resistant (transgenic) crops such as corn, soybean, cotton, canola, sugar beets, and alfalfa. Registered non-agricultural uses include: tree injections, residential spot treatments, aquatic areas, forests, rights of ways, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land.

Application methods vary for glyphosate and include aircraft, various ground equipment, and various handheld equipment. Application types include: aerial spray, ground boom spray, strip treatment, band treatment, broadcast spray, spot treatment, tree injection, stump treatment, and wipe-on/wiper treatments. The maximum single application rate on labels is up to 8 pounds acid equivalent per acre (lb ae/A) (acid equivalents or ae are used to assess the different acid and salt forms of glyphosate) for the following uses: pastures, non-food tree crops, forestry, aquatic areas, and non-crop. However, for agricultural row crop uses, maximum single application rates are 1.55 lb ae/A for aerial applications and 3.75 lb ae/A for ground applications. Maximum annual application rates are generally 6 to 8 lbs ae/A.

The EPA completed a new usage analysis for glyphosate by analyzing agricultural market research data from 2012 to 2016. Approximately 281 million pounds of glyphosate was applied to 298 million acres annually in agricultural settings. Most glyphosate was applied to soybean (approximately 117.4 million lbs applied annually), corn (approximately 94.9 million lbs applied annually), and cotton (approximately 20 million lbs applied annually). Many citrus fruits (*e.g.*, grapefruit, oranges, lemons), field crops (*e.g.*, soybean, corn, cotton), and tree nuts (*e.g.*, almonds, walnuts, pistachios) have the highest percentage of their acres treated with glyphosate.

Approximately 24 million pounds of glyphosate are applied to non-agricultural sites annually, on average. The majority of non-agricultural use is for the homeowner market (approximately 5 million lbs applied annually), turf (approximately 4.9 million lbs applied annually), forestry

(approximately 3.6 million lbs applied annually), and roadways (approximately 3.3 million lbs applied annually).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate. For additional details on the human health assessment for glyphosate, see the *Glyphosate Draft Human Health Risk Assessment for Registration Review*, which is available in the public docket.

1. Risk Summary

The EPA thoroughly assessed risks to humans from exposure to glyphosate from all uses and all routes of exposure and did not identify any risks of concern. Both non-cancer and cancer effects were evaluated for glyphosate and its metabolites, aminomethyl phosphonic acid (AMPA) and N-acetyl-glyphosate. The different components of the EPA's human health risk assessment are described below.

Cancer Assessment

The EPA convened a FIFRA SAP meeting in December 2016 to consult on the carcinogenic potential of glyphosate. Recommendations from the Scientific Advisory Panel meeting were published in March 2017. The EPA revised its cancer assessment based on comments received from the SAP and responded to the SAP in the *Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate*. The EPA's final cancer conclusion and its rationale for reaching this conclusion is described in the *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*. The EPA's final cancer assessment includes the newly published analysis of glyphosate use and cancer incidence in the Agricultural Health Study (AHS). The AHS study is a long-term epidemiological study of over 54 thousand pesticide applicators to investigate the association between pesticide exposures and incidence of various types of cancer and non-cancer outcomes. The EPA's review of the AHS study is described in the *Summary Review of Recent Analysis of Glyphosate Use and Cancer Incidence in the Agricultural Health Study*. The agency has determined that glyphosate is not likely to be carcinogenic to humans and therefore a quantitative cancer assessment was not conducted.

All documents relating to the cancer evaluation for glyphosate are published in the public registration review docket for glyphosate (EPA-HQ-OPP-2009-0361). The deliberations of the glyphosate FIFRA SAP meeting, including agenda, meeting notes, SAP recommendations, the EPA's presentation to the FIFRA SAP, and other supporting documents are published in the glyphosate FIFRA SAP docket (EPA-HQ-OPP-2016-0385) at www.regulations.gov.

The Agency has received a September 27, 2018 petition from the Environmental Working Group, Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farms, Inc. requesting that the agency reduce the tolerance of the pesticide glyphosate in or on oats and modify labels to explicitly prohibit preharvest use on oats. The agency is still reviewing this petition and has issued a Federal Register Notice of Filing for public comment in docket EPA-HQ-OPP-2019-0066. The petition references EPA's cancer evaluation and includes the following arguments:

1) EPA's tolerance for oats is not adequately protective of children, due to the widespread use of glyphosate and a lack of glyphosate residue monitoring data. The petitioners submit results of residue testing from the EWG of glyphosate levels in various granola, instant oat, breakfast cereal, and snack commodities as evidence of this assertion.
2) Glyphosate is a possible carcinogen according to the International Agency for Research on Cancer (IARC), who classified glyphosate as "probably carcinogenic to humans" in 2015.
3) Human studies demonstrate a likely link between glyphosate exposure and non-Hodgkin lymphoma.
4) Animal models, when viewed in total, suggest glyphosate is a rodent carcinogen.
5) Analyses of glyphosate animal studies by the European Food Safety Authority and the European Chemicals Agency were flawed, and the incidence of tumors is higher than reported.
6) Petitioners point to comments sent from the Office of Research and Development, which were sent to the Office of Pesticide Programs (OPP) while the agency's cancer evaluation was being drafted in 2015, as a line of evidence, contending that OPP should have been more circumspect about rejecting IARC's cancer conclusion.
7) EWG calculated its own cancer risk level and proposed that the level protective of children's health is 0.01 milligrams of glyphosate per day. The petitioners contend that EPA's dietary risk assessment is not adequately protective of children.

Since this petition was submitted outside of the public comment period for the human health and ecological risk assessments, which closed on April 30, 2018, EPA has not considered it as a public comment in the preparation this Proposed Interim Registration Review Decision. EPA will respond to this petition concurrent with the development of its Interim Registration Review Decision for glyphosate. The risk findings described herein reflect the conclusions of EPA's December 12, 2017 human health risk assessment.

Dietary (Food + Water) Risks

An acute dietary assessment was not completed because an acute reference dose could not be established due to the absence of observable adverse effects seen in acute studies. A cancer dietary assessment was not conducted because glyphosate is classified as not likely to be carcinogenic to humans.
Long-term toxicity studies in mice, rats, and dogs demonstrate that glyphosate is of very low toxicity following repeated oral exposure. Rabbits were the most sensitive species tested and the endpoint chosen for chronic dietary assessment was based on diarrhea and few/no feces. A

conservative chronic dietary risk assessment was conducted assuming tolerance-level residues, modeled drinking water estimates from direct application to water scenarios, 100% crop treated assumptions, and default modeling parameters. The resulting chronic dietary risk estimates were not of concern. Children 1-2 years old were the most highly exposed population subgroup (chronic population adjusted dose [cPAD] = 23%, where a cPAD above 100% exceeds the agency's level of concern).

Breast Milk Analysis

In response to concerns from certain segments of the public related to the potential presence of glyphosate in human breast milk, the EPA analyzed human breast milk samples collected by the National Children's Study for residues of glyphosate and glyphosate metabolites (N-acetyl-glyphosate and AMPA). A total of 39 samples from 39 mothers were analyzed. Glyphosate and its metabolites were not detected in human breast milk samples. For additional details on the EPA's breast milk analysis and methodology, please view the following documents in the glyphosate registration review docket:

- *Analysis of Human Milk for Incurred Residues of Glyphosate and its Metabolites. ACB Project #B14-46—Updated from Report Dated September 18, 2015* (dated April 26, 2016)
- *Analytical Method for the Determination of N-Acetylglyphosate and Other Analytes in Various Animal Matrices Using LC/MS/MS* (undated)

The results of the EPA's breast milk analysis is consistent with the scientific literature for glyphosate, which indicates that glyphosate does not bioaccumulate in the human body.

Residential Handler Risks

The EPA considered the potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). A quantitative residential handler assessment was not completed due to lack of toxicity from short- and intermediate-term dermal and inhalation routes of exposure. Residential handler risks are not anticipated from currently registered uses of glyphosate.

Residential Post-Application Risks

Post-application dermal and inhalation assessments were not quantitatively assessed due to lack of toxicity. However, a short- and intermediate-term post-application incidental oral exposure assessment was conducted to assess potential risk from two scenarios: 1) for hand-to-mouth behavior on treated lawns and 2) for swimmers via short-term post-application incidental oral exposure to glyphosate from the aquatic use. Post-application incidental oral risk estimates for the turf use were not of concern, with Margins of Exposure (MOEs) ranging from 640 to 290,000, where MOEs below 100 are of concern. Post-application swimmer risk estimates for the aquatic use were not of concern (MOEs range from 210,000 to 2,200,000, where MOEs below 100 are of concern). Therefore, residential post-application risks are not anticipated from currently registered uses of glyphosate.

Non-Occupational Bystander Spray Drift Risks

The EPA assessed the potential for risk to non-occupational bystanders from off-target movement of glyphosate via spray drift, to protect from indirect exposure (*e.g.*, children playing on lawns where residues have deposited next to treated fields). Since glyphosate is registered for use on turf, it was considered whether the existing turf post-application assessment was protective of bystander exposure via spray drift. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The currently registered maximum single agricultural application rate for glyphosate is 8 lbs ae/A (for use on pastures, forestry, non-food tree crops, etc.). The highest fraction of spray drift for any application method immediately adjacent to a treated field results in a deposition fraction of 0.26 of the application rate (from AgDrift modeling). The maximum application rate adjusted by the 0.26 adjustment factor for drift (8 lb ae/A x 0.26 lb ae/A=2.08 lb ae/A) is less than the assessed maximum direct spray residential turf application rate (10.5 lb ae/A). Therefore, the turf post-application assessment is protective for any potential bystander spray drift exposure, and a quantitative spray drift assessment for glyphosate was not required. Therefore, non-occupational bystander spray drift risks are not of concern for glyphosate.

Aggregate Risks

Aggregate risk assessment considers exposure from food, drinking water, and residential exposures combined. The EPA conducted short-term (food, water, residential) and chronic (food and water) aggregate risk assessments. Acute and cancer aggregate risk assessments were not conducted since an appropriate endpoint attributable to a single dose was not identified for the general U.S. population or any population subgroup and glyphosate is classified as not likely to be carcinogenic to humans, respectively. An intermediate-term assessment was not conducted since the short-term assessment is protective of intermediate-term exposure (the endpoints for these durations are identical). Short-term aggregate risks were not of concern (MOE for children = 260, MOE for adults = 1,300, where MOEs below 100 are of concern). The MOE for children represents exposure from chronic dietary (food and water) and incidental oral ingestion exposure from turf use, which was the highest exposure scenario. The MOE for adults represents chronic dietary exposure (food and water) and incidental oral ingestion exposure resulting from aquatic use, the highest exposure scenario.

Chronic aggregate risks were also not of concern. Chronic aggregate exposure is from dietary (food and water) exposure only, based on the use pattern, and are the same as the chronic dietary risk estimates (≤23% cPAD, see dietary section).

Cumulative Risks

The EPA has not made a common mechanism of toxicity to humans finding as to glyphosate and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the EPA did not assess cumulative risks for this assessment.

Occupational Risks

A quantitative occupational exposure assessment was not conducted due to lack of toxicity via the occupational handler and post-application dermal and inhalation routes of exposure. Therefore, occupational risks from currently registered uses of glyphosate are not of concern.

The current restricted entry interval (REI) on the labels is 12 hours or 4 hours, depending on the glyphosate formulation. The current human health risk assessment supports a 4 hour REI for glyphosate the active ingredient, but the different glyphosate formulations were not assessed. According to *PRN 95-3: Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) for Certain Low Risk Pesticides*, certain glyphosate formulations may qualify for a reduced 4 hour REI. Glyphosate registrants may use the existing label amendment process to request a reduction in the existing 12 hour REI to a 4 hour REI on the label, on a formulation by formulation basis.

2. Human Incidents and Epidemiological Analysis

The EPA conducted an extended incident search for glyphosate human health incidents in February 2014. Five pesticide incident data sources were reviewed: Office of Pesticide Programs Incident Data System (IDS; 2008-2012), National Pesticide Information Center (NPIC; 2007-2013), California's Pesticide Incident Surveillance Program (PISP; 2005-2010), National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH/SENSOR; 1998-2009), and the American Association of Poison Control Centers (AAPCC; 2001-2012). Thousands of glyphosate incidents were reported but most reported incidents were minor in severity. The high number of reported incidents across the databases is likely a result of glyphosate being among the most widely used pesticides by volume. Health effects reported in the incident databases include dermal, ocular, and respiratory symptoms and effects are generally mild and resolve rapidly. Data from IDS and NPIC suggest that homeowner mixing/loading/applying (usually due to human error and container leaks of glyphosate products) are responsible for almost half of reported incidents. Data from SENSOR-Pesticides are consistent with IDS and NPIC and show that glyphosate application results in the most reported incidents. Occupational handling of equipment is responsible for most incidents in California's PISP database due to equipment leaks and malfunction. Across SENSOR, IDS, and NPIC, children's exposure was due to post-application exposure, accidental ingestion, and tampering with the product.

The medical-case literature was reviewed, and most accidental ingestion of glyphosate formulations result in mild symptoms. Intentional ingestions caused moderate to severe symptoms and involved multiple organ systems.

The epidemiological literature was also reviewed but most studies were hypothesis-generating in nature. The EPA found there was insufficient evidence to conclude that glyphosate plays a role in any human diseases. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

An updated incident search was conducted in the IDS on October 26, 2018 for new human health incidents. From January 1, 2014 to October 25, 2018, 249 incidents were reported in the Main IDS involving glyphosate. Of these, there were 3 deaths, 24 incidents were classified as major

severity, 216 incidents were classified as moderate severity, 5 incidents were classified as minor severity, and 1 incident had no or unknown effects. Of the three reported deaths, two were suicides and one was described as a "Roundup overdose." From January 1, 2014 to October 25, 2018, 3,123 incidents were reported to Aggregate IDS involving glyphosate; most were classified as minor severity and the rest had no effects or unknown effects.

For more information on reported human incidents, see the *Glyphosate: Tier II Incident Report*, available in the in the public docket for glyphosate.

3. Tolerances

Tolerances are established for residues of glyphosate in/on numerous plant commodities in 40 CFR § 180.364. Glyphosate tolerances range from 0.2 to 400 ppm. The EPA evaluated the glyphosate residue chemistry database to determine if the established tolerances conform to current practices and to determine whether updates were necessary for current crop group/subgroup definitions. The EPA intends to establish new tolerances for various vegetable and fruit groups and subgroups, as listed in Table 1. Upon establishment of these new crop group tolerances, EPA intends to remove the following individual tolerances, since they will no longer be needed: acerola; aloe vera; ambarella; asparagus; atemoya; avocado; bamboo, shoots; banana; biriba; breadfruit; cactus, fruit; cactus, pads; canistel; cherimoya; custard apple; date, dried fruit; durian; feijoa; fig; fruit, stone, group 12; guava; ilama; imbe; imbu; jaboticaba; jackfruit; longan; lychee; mamey apple; mango; mangosteen; marmaladebox; noni; nut, tree, group 14; olive; palm heart; papaya; papaya, mountain; passionfruit; pawpaw; persimmon; pineapple; pistachio; pomegranate; pulasan; rambutan; rose apple; sapodilla; sapote, black; sapote, mamey; sapote, white; soursop; Spanish lime; star apple; starfruit; sugar apple; Surinam cherry; tamarind; vegetable, leafy, brassica, group 5; vegetable, leafy, except brassica, group 4; watercress, upland; and wax jambu.

Table 1. Proposed Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.

Current		Proposed Change		Comment
Commodity	Tolerance (ppm)	Commodity	Tolerance (ppm)	
Soybean, forage	100.0	Soybean, forage	100	change in number of significant figures
Soybean, hay	200.0	Soybean, hay	200	
Soybean, hulls	120.0	Soybean, hulls	120	
Soybean, seed	20.0	Soybean, seed	20	
Fruit, stone, group 12	0.2	Fruit, stone, group 12-12	0.2	update to the current crop group definitions; coconut was excluded from the tree nut crop group tolerances as the residues were not within 5x (coconut tolerance at 0.1 ppm)
Nut, tree, group 14	1.0	Nut, tree, group 14-12 (except coconut)	1.0	
Vegetable, leafy, except brassica, group 4	0.2	Vegetable, leafy, group 4-16	0.2	update to the current crop group definitions
Vegetable, leafy, brassica, group 5	0.2	Vegetable, *Brassica*, head and stem, group 5-16	0.2	

Table 1. Proposed Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.				
Current		Proposed Change		Comment
Commodity	Tolerance (ppm)	Commodity	Tolerance (ppm)	
Several	0.2-0.5--	Vegetable, stalk and stem, subgroup 22A	0.5	
	0.2	Vegetable, leaf petiole, subgroup 22B	0.2	
	0.2	Fruit, tropical and subtropical, edible peel, group 23	0.2	
	0.2	Fruit, tropical and subtropical, small fruit, inedible peel, group 24A	0.2	
	0.2	Fruit, tropical and subtropical, medium to large fruit, smooth, inedible peel, group 24B	0.2	
	0.2	Fruit, tropical and subtropical, large fruit, rough or hairy, inedible peel, group 24C	0.2	
	0.2	Fruit, tropical and subtropical, vine, inedible peel, group 24E	0.2	

In accordance with FFDCA, the Agency will be conducting rulemaking to implement any tolerance changes identified for glyphosate.

4. Human Health Data Needs

No human health data needs have been identified for glyphosate. The human health data required as part of the registration review DCI has been satisfied.

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate. For additional details on the ecological assessment for glyphosate, see the *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*, which is available in the public docket.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for glyphosate. See Appendix D for more details. As such, potential risks for non-listed species only are described below. See section III.C of this document for additional risk characterization.

1. Risk Summary

Terrestrial Risks

To assess risk to mammals, birds, terrestrial invertebrates, and terrestrial plants, the EPA reviewed both registrant-submitted studies and studies from the open literature. When available, formulation-specific data were also considered in addition to data on glyphosate alone.

Mammals

Acute risks to mammals are expected to be low for technical grade glyphosate. Acute risk quotients (RQs) were not calculated for mammals because the lethal dose sufficient to kill 50% of a population (LD_{50}) is greater than the highest concentrations tested (up to 4,800 milligrams acid equivalent per kilogram of bodyweight [mg ae/kg-bw]) in the available acute oral toxicity study. Estimated Environmental Concentrations (EEC)s for all uses except spot treatment are below the highest concentration tested in the available acute oral and acute dietary studies. However, the application rate for spot treatments is adjusted to a per acre basis and conservatively assumes that the entire area is treated at that high rate.

In addition to toxicity studies with technical grade glyphosate, acute dose-based toxicity studies were available for various formulations. RQs exceeded the level of concern (LOC) of 0.5 for one formulation (11.4% glyphosate; acute RQs $\leq$ 2.1) for labeled use on broadcast brush at a rate of 7.2 lb ae/A. Data for most formulations showed LD_{50} values greater than the highest dose tested.

Chronic dietary-based RQs for technical grade glyphosate did not exceed the LOC for any use patterns, except spot treatment (RQs $\leq$ 1.92, where the LOC=1). However, chronic dose-based RQs did exceed the LOC for the following scenarios:

i. application to sugarcane at rates of 2.25 lb ae/A and above (RQ=1.02),
ii. application to most conventional crops by ground at rates of 3.75 lb ae/A and above (RQ $\leq$ 1.21),
iii. application to Roundup-ready crops at the maximum annual rate of 6 lb ae/A (RQs $\leq$1.11),
iv. application to tree crops at a rate of 8 lb ae/A (RQs $\leq$ 1.03),
v. application to food trees and vine, berry, and small fruits at the maximum annual rate of 8 lb ae/A (RQs $\leq$1.60),
vi. application to forestry, pastures, non-crops areas at a rate of 8 lb ae/A (RQs $\leq$ 2.04),
vii. application as spot treatments assuming a rate of 40 lb ae/A (RQs $\leq$ 10.2).

Most chronic dose-based risk exceedances are slightly above the LOC, except for residential spot treatments. The application rate for spot treatment conservatively assumes that the entire acre is treated at a high rate of 40 lb ae/A. Potential risk to mammals from spot treatment use should be limited to residential areas and limited in area.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Potential acute risks to birds from exposure to technical grade glyphosate are likely to be nearer to the level of concern at application rates lower than 8 lb ae/A. There were no mortalities in any of the acute oral or acute dietary avian studies with technical glyphosate (LD_{50} values >3,196.3 mg ae/kg-bw and >4,971 mg ae/kg-diet, respectively). Since definitive LD or LC_{50} values were not determined, RQs were not calculated. EECs for all uses except spot treatment are below the highest concentration tested in the available acute oral and acute dietary studies. However, the application rate for spot treatments is adjusted to a per acre basis and conservatively assumes that the entire area is treated at that high rate.

Regarding the acute toxicity of glyphosate formulations, RQs exceeded the LOC of 0.5 for one formulation (68.5% glyphosate monoammonium salt; acute RQs $\leq$ 1.26, based on an LD_{50} value of 1,131 mg ae/kg-bw for bobwhite quail). Acute avian studies were available for the degradate AMPA and data show it is no more toxic than the parent glyphosate.

Chronic avian RQs were not calculated because the most sensitive endpoint in the avian reproduction study resulted in a non-definitive NOAEC. However, EECs for multiple uses are greater than the lowest concentration tested in the mallard study where effects on body weight were observed (NOAEC <501 mg ae/kg; MRID 48876602). To further characterize the potential for chronic risk from exposure to glyphosate, RQs were calculated using the non-definitive NOAEC from the avian reproduction study with the bobwhite quail where no effects were observed at the highest concentration tested, 830 mg ae/kg-diet. The following scenarios exceed the LOC of 1:

i. application to most conventional crops at the maximum single aerial rate (1.55 lb ae/A), the maximum single ground rate (3.75 lb ae/A), or above,
ii. application to Roundup ready crops by ground at the maximum single rate of 3.75 lb ae/A or above,
iii. application to sugarcane at rates of 2.25 lb ae/A or above,
iv. application to tree crops at rates of 8 lb ae/A,
v. application to food trees and vine, berry, and small fruits at 8 lb ae/A, and
vi. application to forestry, pasture, and non-crop areas at a rate of 8 lb ae/A.

RQs for the scenarios above were marginal (RQs ranged from approximately 1 to $\leq$ 2.5). Given that there were no reported effects up to the highest concentration tested in the bobwhite quail avian reproduction study, these RQs may be conservative for most uses, but to a lesser extent for use on forests, pastures, and non-crop areas. Application as spot treatment at a rate of 40 lb ae/A resulted in higher risk exceedances, but this scenario was conservatively assessed (RQ $\leq$ 11.6). Evidence from multiple studies suggest that exposure to glyphosate may result in decreases in body weight, but reproductive parameters such as number of eggs laid, embryo viability, and eggshell thickness may not be impacted.

Terrestrial Invertebrates (honeybees)

Potential risk to terrestrial invertebrates is uncertain, as acute contact and oral honeybee LD_{50} values are greater than the highest doses tested (103 µg ai/bee for contact, 182 µg ai/bee for oral exposure). Application rates higher than 5.7 lb ae/A exceed the highest tested oral concentrations. Risks to individual bees at application rates lower than 5.7 lb ae/A are expected to be low, but risks are uncertain at rates above 5.7 lb ae/A.

In a colony-level study, no adverse effects were reported based on exposure to residues from an application at a rate of 1.92 lb ae/A.

Data are available for other types of terrestrial invertebrates (predatory mites, earthworms, parasitic wasps) where no effects are reported up to the highest dose tested. The most sensitive endpoint was for predatory mite, and data suggest possible effects up to 69 ft from the edge of

the field for an application rate at 8 lb ae/A, and 16 ft from the edge of the field for an application rate at 3.75 lb ae/A.

Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although the EPA identified the need for certain data to evaluate potential effects on pollinators when initially scoping the registration review for glyphosate, the problem formulation and registration review DCI for glyphosate, were both issued prior to the EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[9]. This 2014 guidance lists additional pollinator studies that were not included in the glyphosate registration review DCI. Therefore, the EPA is currently determining whether additional pollinator data are needed for glyphosate. If the agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for glyphosate, then the EPA will issue a DCI to obtain these data. The pollinator studies that could be required for glyphosate are listed in Table 2 below.

Table 2. Potential Pollinator Data Requirements for Glyphosate

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline	Honey bee adult chronic oral toxicity
Non-Guideline	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

Terrestrial Plants

Exposure to glyphosate may impact non-target terrestrial plants. Risks from runoff due to glyphosate applications are anticipated to be low. Runoff estimated environmental concentrations were lower than the no observable adverse effect level for plants (based on seedling emergence data).

Potential risks to terrestrial plants are primarily from spray drift. Based on vegetative vigor data, dicots are generally more sensitive to glyphosate than monocots. The most sensitive species tested was cucumber, based on vegetative vigor data for a glyphosate formulation where phytotoxicity was observed (leaf discoloration). A spray drift analysis was completed for both ground and aerial application of glyphosate at various application rates up to 8 lb ae/A, assuming

[9] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

default droplet size parameters. Fine to medium droplets were assessed for aerial application and very fine to fine droplets were assessed for ground application (based on the American Society of Agricultural and Biological Engineers' [ASABE] droplet size classification standard). Results for the most sensitive species tested, cucumber, are presented in Table 3.

Given its importance as a critical food resource for the monarch butterfly, the agency also completed a spray drift analysis for common milkweed. Reported toxicity endpoints in the literature for common milkweed are similar to the vegetative vigor endpoints for cucumber, the most sensitive species tested (IC_{25} for cucumber is 0.074 lb ae/A; IC_{25} for common milkweed is 0.126 lb ae/A). Distances from the edge of the field to be below toxicity threshold (i.e., buffer distances) for both cucumber and milkweed are listed in Table 3.

Table 3. Results of spray drift assessment for terrestrial plants for both aerial and ground application of glyphosate at various application rates

Application rate (lb ae/A), assuming 1 application at each rate	Distance from the edge of the field to be below toxicity threshold for most sensitive species tested (cucumber)	Distance from the edge of the field to be below toxicity threshold for the common milkweed	Spray method
1.55	190	118	Aerial (fine to medium droplets)
2.25	282	171	
3.75	466	279	
8	>1,000	620	
1.55	52	33	Ground (very fine to fine droplets)
2.25	79	46	
3.75	128	75	
8	253	157	

Ground applications result in less spray drift than aerial applications in general. For the most sensitive species, cucumber, applications at 8 lb ae/A result in buffer distances of 253 ft for ground application and over 1,000 ft for aerial application. Applications at rates of 3.75 lb ae/A result in much lower buffer distances (128 ft for ground application and 466 ft for aerial application).

Aquatic Risks

To assess potential risk to aquatic organisms, the EPA reviewed both registrant-submitted studies and open literature studies. The EPA also assessed risk from exposure to technical grade glyphosate and for formulated glyphosate, including formulations containing polyoxyethylene tallow amine (POEA). While POEA is not used in glyphosate formulations labeled for aquatic use sites, terrestrial formulations may still contain POEA and may contribute to exposure via runoff. Risk from runoff and spray drift were assessed. Exposure from both terrestrial and aquatic applications were considered.

Data on the degradate aminomethylphosphonic acid (AMPA) were available for fish and aquatic invertebrates and were reviewed as part of the aquatic assessment. Based on existing data,

AMPA appears to be less acutely toxic to aquatic organisms than the parent glyphosate and the existing aquatic assessment is considered protective for exposure to AMPA.

Fish, Aquatic Invertebrates, and Aquatic-Phase Amphibians

Risks to fish, aquatic invertebrates, and aquatic-phase amphibians did not exceed the LOC for exposure to glyphosate alone (acute RQs < 0.01, where the acute LOC = 0.5; chronic RQs ≤ 0.12, where the chronic LOC = 1). Risks are also likely to be low for exposure to formulations containing POEA (acute RQs ≤ 0.07). Formulations that do not contain POEA similarly did not show risks of concern (acute RQs < 0.01).

Aquatic Vascular and Non-Vascular Plants

Risks to aquatic plants did not exceed the level of concern for exposure to glyphosate alone (acute RQs ≤ 0.17, where the LOC=1). Risks are likely to be low for exposure to formulations containing POEA via terrestrial applications (acute RQs ≤ 0.68). Risks exceed the level of concern for exposure to formulations without POEA for applications to aquatic environments (acute RQs ≤ 2.6). This is not surprising, given that some glyphosate formulations are tailored to treat aquatic weeds.

Evaluation of risk to terrestrial plants from exposure to spray drift via glyphosate formulations is described in the terrestrial plant section, and the calculated distances off-field to be below toxicity threshold would apply to emergent aquatic vegetation as well as terrestrial plants. For emergent aquatic vascular plants, there is potential for risk from exposure to spray drift from terrestrial uses (distance from the edge of the field to below toxicity threshold is over 1,000 ft, for application rates at 8 lb ae/A, see table 2).

2. Ecological Incidents

A review of the Ecological Incident Information System (EIIS) and the Avian Monitoring Information System (AIMS) was conducted on February 21, 2014. A search of the Office of Pesticide Incident Data system (IDS) for aggregated incidents (i.e., registrant-reported incidents) was conducted on February 27, 2014. Incidents in EIIS are classified as "possible," "probable," and "highly probable." Incidents in AIMS are classified as "possible," "probable," "likely," "highly likely," and "certain." The majority of the glyphosate incidents are for terrestrial plants, fewer incidents were reported for terrestrial and aquatic wildlife.

Terrestrial plant incidents

Plant incidents for glyphosate and its various salt forms involved either direct treatment or spray drift and resulted in either plant damage or mortality. Approximately 602 individual plant incidents were reported, and 724 aggregate incidents were reported. Reports were classified from "possible" to "highly probable." Most plant incidents involved spray drift onto adjacent agricultural crops and grass. There were a few incidents of trees being damaged or killed. There was one incident which involved use on a right-of-way that was classified as highly probable.

Terrestrial wildlife incidents

Five wildlife incidents were reported for glyphosate for uses on rangeland/pasture, home/lawn, and a tree farm. One consisted of accidental misuse on corn where an unknown bird was reported as dead. Two incidents classified as "possible" involved mortality to three birds from drift and mortality to several dogs from runoff. No additional details were provided for the dog mortalities. For the bird mortalities, other chemicals were applied at the same time, including atrazine, s-metolachlor, and permethrin. One incident involved honeybees and was classified as "possible" where it was reported that an herbicide containing sulfometuron methyl and glyphosate was applied near flowering areas and twitching or dead bees were observed near three hives. One "probable" incident reported incapacitation of two iguanas following ingestion of dandelions sprayed with glyphosate. In the IDS aggregate database, there were 38 reports of wildlife incidents, but additional details were not available.

Aquatic incidents

One "possible" 2003 incident involved 10 dead goldfish, 2 incapacitated fish, and other fish observed "gasping" at the water surface; investigators reported it was not possible to determine a reason for the fish kill due to lack of water measurements. Eleven fish incidents were reported from 1990 to 2003 with classifications ranging from "possible" to "highly probable." One "highly probable" incident involved misuse where thousands of shad were killed. Four other incidents of misuse were also reported. Two fish kill incidents were reported where glyphosate was applied directly to the fish pond, in both cases investigations indicated that elevated ammonia and reduced dissolved oxygen may have been reason for the fish kill. One incident involved glyphosate being applied to the perimeter of a pond and fish kills were reported 2 months later; the report indicated that overstocking and improper disolved oxygen may have killed the fish. In one incident, glyphosate was applied to 80 acres next to a fish pond, when it rained the next day, 700 fish were found dead, but no other details were provided.

Incident update

As of 2017, all ecological incidents are migrated and combined into IDS. An updated search for new ecological incidents since 2014 was conducted in IDS on November 26, 2018. There were 24 reported incidents of on-site crop damage from application of glyphosate in combination with other pesticides. Twelve incidents were on treated corn and were classified as "possible" to "probable"; the adverse effects observed in corn included crop injury, discoloration, or death. There were 12 incidents of crop damage on soybean, incident classifications ranged from "possible" to "probable" and adverse effects observed were browning/death or discoloration/bleaching.

There were 5 reported incidents of off-target spray drift damage. One "probable" incident in 2014 involved drift onto a nearby vineyard from a non-crop area application nearby and resulted in the withering and yellowing of grape leaves. Another "possible" incident in 2014 involved dead or dying bees on a sidewalk from application of glyphosate and pendimethalin in the area; no further details were provided. A "possible" incident in 2015 involved drift from a glyphosate ditch area application which resulted in death in 7 bee hives nearby a week later; the beekeeper reported loss of over 100,000 bees. Another "probable" incident in 2015 involved drift from a

field corn application which resulted in phytotoxicity in a garden nearby. A "possible" incident in 2017 involved drift damage to 20 acres of roses and 22 thousand potted roses; multiple herbicide applications were reported nearby by multiple growers.

3. Ecological and Environmental Fate Data Needs

The ecological effects data required as part of the glyphosate registration review DCI were received and found to be adequate for risk assessment. As noted in Table 1, pollinator data may still be needed. The agency will issue a DCI for pollinator data as part of a separate action if it determines that additional pollinator data are necessary to help make a final registration review decision for glyphosate.

C. Risk Characterization

Birds and Mammals

Potential risks were identified for mammals and birds feeding on foliar dietary items treated with glyphosate. There were marginal risk exceedances for applications at the maximum single aerial application rate of 1.55 lb ae/A, the maximum single ground application rate of 3.75 lb ae/A, application to sugarcane, and applications to tree crops, forests, pastures, and non-crop areas at 8 lb ae/A. Risks from these scenarios are likely limited to the treated field and areas near the treated field. Risk to mammals and birds were primarily for application as spot treatment. Spot treatments are limited to residential areas and limited to small areas, so risks from this use are likely spatially limited. In addition, the risk assessment assumes that birds and mammals will consume food items treated with glyphosate as 100% of their diet, this is unlikely to occur from spot treatment application.

According to USDA, use on non-food tree crops, forestry, pastures, and non-crop areas are also geographically limited.[10] The high application rate of 8 lb ae/A intended for these uses are for small spot treatments in highly concentrated and localized areas for management of invasive weeds and for conservation purposes on non-agricultural lands. The application methods used for these sites are unlikely to drive drift, as application is usually by small mechanically-pressurized or handheld equipment. Exposure to birds and mammals under such conditions are likely to be localized and minimal.

Non-food tree crop applications are intended for private forestry management. According to USDA, glyphosate is applied in this setting as part of a tank mix for weed resistance management, and the rate used is no more than 4.5 or 5 lbs ae/A. Application for forestry management is usually made by helicopter equipped with drift control technologies, including micro-foil boom and raindrop nozzles which allow for precise applications. Glyphosate is also applied to conifer and hybrid cottonwood establishments in the Pacific Northwest, and recommended use rates for site preparation range from 1.5 to 3 lb ae/A.

[10] See USDA's comments on the glyphosate ecological risk assessment in the glyphosate registration review docket at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-1618

Glyphosate use in pastures is for renovation and habitat restoration efforts. According to USDA, glyphosate is applied at 2.25 lb ae/A for forage renovation (to convert common bermudagrass to hybrid bermudagrass) with 2 consecutive fall applications. In natural areas or utility rights of way, glyphosate rates may reach 4 lb ae/A. Application above 4 lb ae/A is usually applied by handgun for spot treatment of invasive weeds, such as cogon grass, and are not likely to drive risk concerns.

Since these uses are very localized and application to these use sites are either with lower application rates than assessed or done with application equipment that is unlikely to contribute to spray drift, risk to mammals and birds from these uses is expected to be lower than estimated.

Terrestrial and Aquatic Plants

Consistent with its mode of action as an herbicide, risk to non-target terrestrial and aquatic plants were primarily from spray drift and the resulting buffer distances were heavily dependent on the application rate used (Table 2). The maximum labeled single application rate for ground application to agricultural row crops is 3.75 lb ae/A; at this rate, the distance from the edge of the field to get below toxicity threshold is 128 ft. The maximum labeled single application rate for aerial application to agricultural row crops is 1.55 lb ae/A; at this rate, the distance from the edge of the field to get below toxicity threshold is 190 ft.

The EPA recently completed an updated analysis of glyphosate usage (see the *Glyphosate: Response to Comments, Usage, and Benefits* document), and data from 2012 to 2016 indicate that for many crops, the average single application rates used by growers are even lower than the application rates assessed by the EPA for ground and aerial row crop applications. Average single application rates used by growers vary from crop to crop but range from 0.67 lb ae/A for canola to 1.84 lb ae/A for table grapes. The majority of glyphosate is applied to corn (approximately 94.9 million lb ae applied annually) and soybean (approximately 113.9 million lb ae applied annually). The average single application rate used for corn is 0.95 lb ae/A and the average single application rate used for soybean is 0.97 lb ae/A. If average application rates are close to typical grower practices, spray drift risk to non-target terrestrial and aquatic plants from row crop applications is expected to be lower than estimated.

For detailed crop by crop usage and rate information, see the *Glyphosate: Response to Comments, Usage, and Benefits* document in the glyphosate docket at www.regulations.gov.

Aquatic Uses

USDA submitted additional information on aquatic applications of glyphosate (2018). Application of glyphosate in aquatic use sites at rates of 8 lb ae/A are for perennial grass control (ex., the invasive torpedograss in Florida). Application at the 8 lb ae/A rate occurs only once per site per year, and aerial applications in such instances are atypical. Perennial grasses like *Arundo* (giant reed) and *Phragmites* (common reed) can be controlled with lower rates and with one application per year. Programs to control giant salvinia (an invasive aquatic fern) in Louisiana involve multiple applications of glyphosate at 1-2 lb ae/A, up to the yearly maximum of 8 lb ae/A. As such, risk to non-target organisms from application to aquatic use sites would be geographically limited.

To view the information submitted from USDA on the non-agricultural uses described previously, please visit the glyphosate public docket at www.regulations.gov (EPA-HQ-OPP-2009-0361-1618).

D. Benefits Assessment

Glyphosate is the most commonly used agricultural herbicide in the United States, in terms of area treated. It is a broad-spectrum herbicide that controls broadleaf, sedge, and grass weeds with minimal residual toxicity to crops or non-target vegetation. Glyphosate is a unique herbicide as it is the only herbicide classified as a Group 9 herbicide by the Weed Science Society of America (WSSA). Glyphosate is a relatively inexpensive herbicide to apply in agricultural situations, with the cost of applications to most crops ranging $1to $13 per acre.

Glyphosate is registered for use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial, and residential areas. Current glyphosate-resistant field crops include soybean, corn, cotton, canola, alfalfa, and sugar beet. Many of these crops, such as corn, cotton, soybean, and sugar beet, have exceptionally high percentages of their acreage treated with glyphosate (approximately 90 percent of acres treated in each crop). Genetically-engineered (transgenic) glyphosate-resistant (GR) varieties of these crops can be sprayed over-the-top with minimal or no crop phytotoxicity, and glyphosate may also be used as a pre-plant burndown in many of these crops. On average, 84 percent of glyphosate applied in agricultural settings, in terms of pounds, is applied to soybeans, corn, or cotton per year.

Glyphosate is also beneficial as part of weed control programs in orchards and specialty crops. Glyphosate use is prevalent in orchard and vineyards floor management and most acres of crops such as tree nuts, citrus, and grapes are treated with glyphosate. Glyphosate is the most diverse herbicide in orchard floor management because it may be used for under tree weed control, chemical wiping, chemical mowing, and spot treatment. Since glyphosate controls a broad spectrum of weeds and does not have residual soil activity, it can be used to control emerged weeds prior to planting high value crops such as fruits and vegetables, where growers sometimes have limited weed control options.

Glyphosate is also important for noxious and invasive weed control in aquatic systems, pastures/rangelands, public lands, forestry, and rights-of-ways. Invasive weeds controlled by glyphosate include cattails and water hyacinth, which can impede water flow and impede irrigation. Improper weed management can cause water to stagnate, which provides a breeding habitat for mosquitos, therefore effective weed control is important for controlling mosquito-borne diseases. Glyphosate is also important for habitat restoration efforts. It is used to control invasive annual, perennial, and woody plants in riparian habitats and rangeland. Glyphosate use in rights of ways helps keep roadways and railroad tracks safe by protecting the stability of the surface, maintaining visibility for operators, and allowing for the distribution of goods, services, and utilities (gas and electric). Glyphosate is the top active ingredient used to control invasive species in the United States.

Glyphosate is a versatile active ingredient and can be applied with many different types of application equipment depending on the needs of the user. In addition to the broadcast spray applications, it can be applied via application methods such as cut stump treatment, stem/tree injection, wick applications, spot treatment, under hooded sprayers, and as a directed spray.

For more information on the benefits of glyphosate, see the *Glyphosate: Response to Comments, Usage, and Benefits* and the 2018 comment from USDA in the glyphosate public docket (EPA-HQ-OPP-2009-0361-1618)

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The EPA did not identify any human health risks from exposure to any use of glyphosate. The agency identified potential risk to mammals and birds, however these risks are expected to be limited to the application area or areas near the application area. The EPA identified potential risk to terrestrial and aquatic plants from off-site spray drift, consistent with glyphosate's use as a herbicide.

Glyphosate is a versatile herbicide that provides a broad spectrum of weed control across numerous agricultural and non-agricultural sites. Glyphosate is generally inexpensive in agricultural settings. Glyphosate is important in the management of invasive/noxious weeds and is essential in habitat restoration efforts for rangeland and pastures. It is used for weed management for rights-of-ways, forestry, industrial settings, residential areas, and aquatic environments.

The EPA concludes that the benefits outweigh the potential ecological risks when glyphosate is used according to label directions. To reduce off-site spray drift to non-target organisms, the EPA is proposing certain spray drift management measures. To preserve glyphosate as a viable tool for growers and combat weed resistance, the EPA is also proposing that herbicide resistance management language be added to all glyphosate labels. The EPA is also proposing certain labeling clean-up/consistency efforts to bring all glyphosate labels up to modern standards. The EPA has discussed these measures with the Joint Glyphosate Task Force, a registrant consortium, which does not oppose the proposed risk mitigation outlined herein.

1. Spray Drift Management

The agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all glyphosate products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate.

The agency is proposing the following spray drift mitigation language to be included on all glyphosate product labels for products applied by liquid spray application. The proposed spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is providing recommendations which allow glyphosate registrants to standardize all advisory language on glyphosate product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once effective.

- Applicators must not spray during temperature inversions.
- For aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor blade diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground and aerial applications, select nozzle and pressure that deliver "fine" or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1).

The Agency's goal is to manage off-target spray drift from applications of glyphosate while continuing to preserve glyphosate's utility for growers and allow growers continued flexibility when making applications. The agency assessed the potential impact on growers of the proposed spray drift management restrictions and has determined that these measures are not expected to substantially reduce the benefit of glyphosate to users. Prohibiting glyphosate applications during temperature inversions may impact the usability of glyphosate products by reducing the amount of time users have to apply glyphosate, but growers can switch to other products if they encounter temperature inversions.

The EPA considered the impact of requiring "fine" or coarser droplets (*i.e.*, requiring growers to deliver droplets no smaller than "fine") on glyphosate labels and has determined that such a requirement is not likely to affect the efficacy of glyphosate when used alone since it is systemic. Glyphosate is a compound that is frequently tank mixed with other herbicides. Because the proposed language provides flexibility with droplet size for tank mixed partners, the EPA does not expect there would be concerns for tank mixing with other herbicides. However, since glyphosate can be applied as a burndown treatment, insecticides may be included in the tank mix. Insecticides are generally considered to provide better efficacy with smaller droplets. The EPA is uncertain if requiring "fine" or coarser droplets will impact the efficacy of insecticides tank mixed with glyphosate because some insecticides could be more effective at droplet sizes smaller than "fine" (such as "very fine" or "extremely fine"). If reduced efficacy occurred, the agency would expect growers to respond by increasing the application rates (if allowed by the label), increasing the number of applications, increasing the application rates of tank mix partners, making additional applications, or switching to a different active ingredient.

In addition to including the spray drift restrictions on glyphosate labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all glyphosate labels where such information currently appears. The proposed new language above, which cites ASABE S572.1, eliminates the need for VMD information. The agency is also proposing the addition of a non-target organism advisory statement. The protection of pollinating organisms is a priority for the agency. It is possible that pollinators and other non-target organisms may be indirectly impacted from effects on forage and habitat. It is the agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, the EPA is proposing non-target organism advisory language to be placed on glyphosate labels to address this potential concern.

2. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.[11] Consistent with the Notice, the EPA is proposing the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID.

The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide resistant weeds have been known since the 1950s, the number of species and their geographical extent, has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide resistant weeds, both in mitigating established herbicide resistant weeds and in slowing or preventing the development of new herbicide resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

The EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

3. Non-target Organism Advisory Statement

The protection of pollinators and other non-target organisms is a priority for the agency. While the agency did not identify risks to individual bees from glyphosate applications at rates below 5.7 lb ae/A, risks to terrestrial invertebrates at higher application rates are uncertain. In addition,

[11] PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship"

glyphosate may impact non-target plants via spray drift and impact nectar sources and habitat for pollinators and other non-target organisms. EPA is proposing a non-target organism advisory statement to alert users of potential impact to non-target organisms: "This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."

4. Label Consistency Measures

There are currently 555 Section 3 registrations and 37 Section 24(c) registrations for glyphosate. Labels directions for glyphosate vary significantly from label to label, and newer stamped labels in general have better instructions than older labels. The EPA is proposing to update all glyphosate labels to modern standards. The components of the label the agency proposes to update are as follows: the maximum application parameters, the environmental hazards statement for aquatic use, and clarification on rotational crop timing. In addition, the agency is providing guidance to glyphosate registrants on acceptable marketing statements.

Maximum Application Parameters

In 2013, at the agency's request and in preparation for risk assessment, the Joint Glyphosate Task Force, a consortium of glyphosate registrants, created a *Use Summary Matrix*, which was intended to summarize all use sites being supported as part of registration review and outline important application parameters such as maximum single and yearly application rates. EPA's risk assessments for glyphosate were based on maximum application parameters as described in the *Use Summary Matrix*. EPA is proposing that maximum labeled rates on current labels be consistent with the maximum application rates that were assessed by the agency and supported by the Joint Glyphosate Task Force. These maximum application parameters are described in Appendix C of this document.

Many older glyphosate labels do not define any maximum application parameters. EPA proposes that maximum application parameters be clearly defined and must not exceed the maximum application parameters as described in Appendix C. It is not EPA's intention to change the current application rates on glyphosate labels, but the agency is proposing to define the rate limits in order to establish better consistency and clarity on labels. Appendix C lists the maximum application parameters by use site for both aerial and ground application.

Statements for Aquatic Uses

The EPA is proposing to update the environmental hazards statements for aquatic use products to be consistent with modern standards and to be in line with newer pesticide labels. The glyphosate Reregistration Eligibility Decision (RED) issued in 1993 specified that glyphosate labels formulated for aquatic use have language intended to warn users of potential fish suffocation for aquatic applications. The EPA is proposing to update the existing language to be consistent with current labeling guidelines (see the EPA's Label Review Manual). Proposed environmental hazards statements are listed in table 4.

In addition, the agency is proposing an additional statement under "directions for use" for aquatic use labels to instruct users to apply in strips to help avoid oxygen depletion when emerged weed infestations cover the total surface area of an impounded water body; the proposed statement also appears in table 4. These statements already appear on some newer labels and the agency is proposing to apply these statements to all labels.

Table 4. Proposed Statements for Glyphosate for Aquatic Use

Product Type	Proposed Statement
Environmental hazards: for labels with terrestrial uses only	"Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with aquatic uses only	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with both aquatic and terrestrial uses	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Directions for use for aquatic uses	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."

Clarification on Rotational Crop Timing

Many glyphosate labels lack instructions for crop rotation. The EPA is proposing to clarify that treated fields may be rotated to a labeled crop at any time. For fields being rotated to a non-labeled crop, any glyphosate application must be made a minimum of 30 days prior to planting.

Label Claims

During meetings with the agency in 2018, the Joint Glyphosate Task Force proposed to clarify on existing labels a statement about how glyphosate works. The following statement is proposed: "Glyphosate works by targeting an enzyme that is essential for plant growth." The proposed revision is consistent with the requirements of 40 CFR § 156.10(a)(5). Registrants may use alternate claims, as long as alternate claims meet labeling requirements. Registrants can refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims prior to submitting updated labels for registration review.

B. Tolerance Actions

The EPA is proposing that the number of significant figures be modified for several tolerances, and that new tolerances be established for various vegetable and fruit groups and subgroups. The new tolerance groupings remove the need for certain older tolerances, which are proposed to be deleted. The Agency will issue a Federal Register notice announcing these proposed tolerance changes under FFDCA following issuance of an Interim Decision for glyphosate. Refer to section III.A.3 of this document for the proposed tolerance changes.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR § 155.56 and 155.58, the agency is issuing this Proposed Interim Registration Review Decision. Except for the EDSP, ESA and pollinator components of this case, the agency has made the following Proposed Interim Registration Review Decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A. and Appendices B and C.

In this proposed interim registration review decision, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate, nor is it making a complete endangered species finding or a complete assessment of effects to pollinators. Although the agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate. The agency's final registration review decision for glyphosate will be dependent upon the result of the agency's ESA assessment and any needed Section 7 consultation with the Services, an EDSP FFDCA section 408(p) determination, and an assessment of non-target exposure to pollinators (bees).

D. Data Requirements

No additional data are required as part of this proposed interim registration review decision. The EPA will consider requesting the glyphosate registrants to submit pollinator data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this proposed interim registration review decision for glyphosate and will allow a 60-day comment period on the proposed interim decision. If there are no significant comments or additional information submitted to the docket during the comment period that leads the agency to change its proposed interim decision, the EPA may issue an interim registration review decision for glyphosate. However, a final decision for glyphosate may be issued without the agency having previously issued an interim decision. A

final decision on the glyphosate registration review case will occur after: 1) an EDSP FFDCA section 408(p) determination, 2) an endangered species determination under the ESA and any needed Section 7 consultation with the Services, and 3) a more in-depth assessment of non-target exposure to pollinators, if determined to be necessary.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued the glyphosate registrants must submit amended labels that include the label changes described in Appendices A, B, and C. The revised labels must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision.

Appendix A: Summary of Proposed Actions for Glyphosate

Registration Review Case#: 0178
PC Codes: 103601, 103604, 103605, 103607, 103608, 103613, 417300
Chemical Type: herbicide
Chemical Family: glycine derivative
Mode of Action: targets the 5-enolpyruvyl-3-shikimate phosphate synthase enzyme

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment (used to briefly clarify or elaborate on risk or mitigation)
Terrestrial and aquatic plants	Spray drift	Foliar absorption	Acute Chronic	Survival, biomass	Require enforceable spray drift management language; updated environmental hazards language	
Birds	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth	Require enforceable spray drift management language	Risks are likely limited to the field and areas near the application field.
Mammals	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth and reproduction	Require enforceable spray drift management language	Risks to are likely limited to the field and areas near the application field.
Terrestrial invertebrates	Residues on nectar sources (via deposition or spray drift)	Dietary	Acute Chronic	Effects on nectar sources of terrestrial invertebrates	Non-target organism environmental hazards language	Risks to bees are uncertain at application rates higher than 5.7 lb ae/A. The agency may require additional pollinator data to fully assess risk to terrestrial invertebrates.

Appendix B: Proposed Labeling Changes for Glyphosate Products

Description	Proposed Label Language for Glyphosate Products	Placement on Label
	End Use Products	
Mode/Mechanism of Action Group Number		Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Non-target Organism Advisory Statement	"NON-TARGET ORGANISM ADVISORY STATEMENT: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
Environmental Hazards Statement for Aquatic Use	*For labels without aquatic uses:* "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with aquatic uses only:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with both aquatic and terrestrial uses:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air	Environmental Hazards

Description	Proposed Label Language for Glyphosate Products	Placement on Label
	over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."	
Aquatic Use Statement	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."	Directions for Use
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action **(Applies to all products delivered via liquid spray applications)**	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Rotational crop information	"Treated fields may be rotated to a labeled crop at any time. For treated fields being rotated to a non-labeled crop, application must be made a minimum of 30 days prior to planting."	Directions for Use
Label claims	"Glyphosate works by targeting an enzyme that is essential for plant growth." [Alternate claims, if used, must meet labeling requirements. Refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims.]	Product Information

Description	Proposed Label Language for Glyphosate Products	Placement on Label
Clarification of application rates	Ground and aerial applications rates on the labels must not exceed the maximum application parameters as noted in Appendix C of this document, which were maximum application parameters assessed by the EPA. Application rates may only be clarified for uses that are currently approved on labels.	Directions for Use
Mandatory Spray Drift Management Language for all products delivered via liquid spray application and allow aerial application	**"SPRAY DRIFT** **Aerial Applications:** • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a fine or coarser droplet size (ASABE S572.1). • Applicators must use ½ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Aerial Applications," and before use rates and or application instructions
Enforceable Spray Drift Management Language for products that allow airblast applications	**"SPRAY DRIFT** **Airblast Applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer rows. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Airblast Applications"
Enforceable Spray Drift Management Language for products that are applied as liquids and allow ground boom applications	**"SPRAY DRIFT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a fine or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Ground Boom Applications"

Enforceable Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	"**SPRAY DRIFT** **Boom-less Ground Applications:** • Applicators are required to use a fine or coarser droplet size (ASABE S572.1) for all applications. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Spray Drift" under the heading "Boom-less Applications"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	"**SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels,* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which can cause small droplets to remain suspended in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They can begin to form in late afternoon/early evening and often continue into the morning. Their presence can be indicated by ground fog. If fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	"**SPRAY DRIFT** **Boom-less Ground Applications:** • Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	"**SPRAY DRIFT** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C. Proposed Maximum Application Rates for Glyphosate Ground and Aerial Application

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Round-up Ready 2 Yield Soybeans	3.75	1.55	6
Root Tuber Vegetables: arracacha, arrowroot, carrot, chinese artichoke, Jerusalem artichoke, beet (garden), burdock, canna, cassava (bitter and sweet), celeriac, chayote (root), chervil (turnip-rooted), chicory, chufa, dasheen (taro), galangal, ginger, ginseng, horseradish, leren, kava (turn-rooted), parsley (turnip-rooted), parsnip, potato, radish, rutabaga, oriental radish, salsify, skirret, sweet potato, tanier, turmeric, turnip, wasabi, yacon, yam bean, true yam	3.75	1.55	6
Rangelands	0.38	0.38	2.25
Pome Fruits: including apple, crabapple, loquat, mayhaw, pear, oriental pear, quince	3.75	1.55	8
Pastures	8	8	8
Oilseed Crops: borage, buffalo gourd, calendula, canola, castor oil plant, chinese tallow tree, crambe, cuphea, echium, euphorbia, evening primrose, flax (seed), gold of pleasure, hare's ear mustard, jojoba, lesquerella, meadow foam, milkweed, mustard (seed), niger (seed), oil radish, poppy seed, rapeseed, rose hip, safflower, sesame, stokes aster, sunflower, sweet rocket, tallow wood, tea oil plant, veronia.	3.75	1.55	6
Non-Food Tree Crops: pine, poplar, eucalyptus, christmas trees, other non-food tree crops	8	8	8
Miscellaneous Tree Food Crops: cactus (fruit and pads), palm (heart, leaves, oil)	3.75	1.55	8
Miscellaneous Crops: aloe vera, bamboo shoots, globe artichoke, okra, peanut (ground nut), strawberry, sugar beet, asparagus, pineapple	3.75	1.55	6
Legume Vegetables: Succulent varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, field pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea; Soybean (immature seed); Sword bean. Dry varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean);	3.75	1.55	6

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Soybean (immature seed); Sword bean Dry varieties of Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea			
Leafy Vegetables: Amaranth (Chinese spinach); Arugula (roquette); Beet greens; Cardoon; Celery; Chinese celery; Celtuce; Chaya; Chervil; Edible-leaved chrysanthemum; Garland chrysanthemum; Corn salad; Cress (garden and upland); Dandelion; Dock (sorrel); Dokudami; Endive (escarole); Florence fennel; Gow kee; Lettuce (head and leaf); Orach, Parsley; Purslane (garden and winter); Radicchio (red chicory); Rhubarb; Spinach; New Zealand spinach; Vine spinach; Swiss chard; Watercress (upland); Water spinach	3.75	1.55	6
Herbs and Spices: Allspice, Angelica, Star anise, Annatto (seed), Balm, Basil, Corage, Burnet, camomile, Caper buds, Caraway, Black caraway, Cardamom, Cassia bark, Cassia buds, Catnip, Celery seed, Chervil (dried), Chive, Chinese chive, Cilantro (leaf), Cilantro (seed), Cinnamon, Clary, Clove buds, Coriander leaf (cilantro or Chinese parsley), Coriander seed (cilantro), Costmary, Cumin, Curry (leaf), Dill (dillweed), Dill (seed), Epazote, Fennel seed (common and Florence), Fenugreek, White ginger flower, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage (leaf and seed), Mace, Marigold, Marjoram (including oregano), Mexican oregano, Mioga flower, Mustard (seed), Nasturtium, Nutmeg, Parsley (dried), Pennyroyal, Pepper (black and white), Pepper leaves, Peppermint, Perilla, Poppy (seed), Rosemary, Rue, Saffron, Sage, Savory (summer and winter), Spearmint, Stevia levaes, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood	3.75	1.55	6
Grass/Turfgrass/Sod Production	3.75	1.55	6
Grain Sorghum	3.75	1.55	6
Fruiting Vegetables: Eggplant; Groundcherry (Physalis spp); Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato	3.75	1.55	6
Forestry	8	8	8
Fallow	3.75	1.55	6
Cucurbits Vegetables/Fruit: Chayote (fruit); Chinese waxgourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Edible gourd (includes hyotan, cucuzza, hechima, Chinese okra); Melons (all); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); Muskmelon (includes cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey ball melon, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon); Pumpkin; Summer squash (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); Winter squash (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); Watermelon	3.75	1.55	6

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Cotton	3.75	1.55	6
Corn (Field, Seed, Silage, Popcorn)	3.75	1.55	6
Conservation Reserve Program	3.75	1.55	6
Citrus Fruit Crop: All cultivars, varieties and/or hybrids of Calamondin; Chironja; Citron; Citrus hybrids; Grapefruit (including Japanese summer); Kumquat; Lemon; Lime (including Australian desert lime, Australian finger lime, Australian round lime, Brown river finger lime, Mount white, New Guinea wild, Russell river, sweet, and Tahiti); Mandarin (including Mediterranean and Satsuma); Orange (all); Pummelo; Tangelo; Tangerine (Mandarin); Tangor; Uniq Fruit (ugli)	3.75	1.55	8
Cereal and Grain Crop: barley, buckwheat, millet, oats, rye, quinoa, teff, teosinte, triticale, wild rice, rice, feed barley, wheat	3.75	1.55	6
Bulb Vegetables: All cultivars, varieties and/or hybrids of Chive (fresh leaves, including Chinese chive); Daylily (bulb); Elegans hosta; Fritillaria (bulb and leaves); Garlic (bulb, including great-headed and serpent garlic); Kurrant, Leek (including lady's and wild leek); Lily (bulb); Onion (including Beltsville bunching, bulb, Chinese bulb, fresh, green, macrostem, pearl, potato bulb, tree tops and Welsh onion tops); Shallot (bulb and fresh leaves)	3.75	1.55	6
Brassica Vegetable: Broccoli; Chinese broccoli (gai lon); Broccoli raab (rapini); Brussels sprouts; Cabbage; Chinese cabbage (bok choy); Chinese cabbage (napa); Chinese mustard cabbage (gai choy); Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens	3.75	1.55	6
Round-up Ready Flex Cotton	3.75	1.55	6
Round-up Ready Cotton	3.75	1.55	6
Round-up Ready Corn (GA-21)	3.75	1.55	6
Round-up Ready Corn 2 (NK603)	3.75	1.55	6
Round-up Ready Alfalfa	1.55	1.55	6
Round-up Ready Sugarbeets	3.75	1.55	6
Tropical/Subtropical Trees/Fruits: Ambarella; Atemoya; Avocado; Banana; Barbados cherry (acerola); Biriba; Blimbe; Breadfruit; Cacao (cocoa) bean; Canistel; Carambola (starfruit); Cherimoya; Coffee; Custard apple; Dates; Durian; Feijoa; Figs; Governor's plum; Guava; Ilama; Imbe; Imbu; Jaboticaba; Jackfruit; Longan; Lychee; Mamey apple; Mango; Mangosteen; Marmaladebox (genip); Mountain papaya; Noni (Indian mulberry); Papaya; Pawpaw; Plantain; Persimmon; Pomegranate; Pulasan; Rambuttan; Rose apple;	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Sapodilla; Sapote (black, mamey, white); Spanish lime; Soursop; Star apple; Sugar apple; Surinam cherry; Tamarind; Tea; Ti (roots and leaves); Wax jambu			
Tree Nut Crops: Cultivars, varieties, and/or hybrids of African nut-tree; Almond; Beechnut; Brazil nut; Brazilian pine; Bunya; Burr oak; Butternut; Cajou nut; Candlenut; Cashew; Chestnut; Chinquapin; Coconut; Coquito nut; Dika nut; Ginkgo; Guiana chestnut; Hazelnut (Filbert); Heartnut; Hickory nut; Japanese horse-chestnut; Macadamia nut; Mongongo nut; Monkey-pot; Monkey puzzle nut; Okari nut; Pachira nut; Peach palm nut; Pecan; Pequi; Pili nut; Pine nut; Pistachio; Sapucaia nut; Tropical almond; Walnut (black, English); Yellowhorn	3.75	1.55	8
Sweet Corn	3.75	1.55	6
Sugar Cane	3.75	2.25	6
Stone Fruit: All cultivars, varieties and/or hybrids of Apricot; Cherry (sweet and tart); Nectarine; Olive; Peach: Plum/Prune (all types); Plumcot	3.75	1.55	8
Round-Up Ready Canola (Winter Varieties)	1.55	1.55	6
Soybeans	3.75	1.55	6
Sweet Corn with Round-Up Ready 2 Technology	3.75	1.55	6
Round-Up Ready Canola (Spring Varieties)	1.55	1.55	6
Vine Crops: grapes (raisin, table, wine), hops, passion fruit, kiwi	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Non Crop: Airports, airfields, apartment complexes, commercial sites, ditch banks, driveways, ramps, alleys, lanes, paths, trails, sidewalks, walkways, access roads, farm roads, highways (including aprons, medians, guardrails, and rights-of-way), paved areas and prior to paving, dry ditches, dry canals, fences and fencerows, golf courses, greenhouses, industrial sites, landscape areas, lumber yards, manufacturing sites, municipal sites, natural areas, office complexes, ornamentals, parks, campgrounds, sports areas, tennis courts, parking areas, cemeteries, petroleum or other tank farms and pumping installations, refineries, around telephone and communications equipment, public areas, drive-in theaters, railroads (including ballasts, shoulders, crossings and spot treatments), recreation areas, residential areas, rights-of-way, roadsides, firebreaks, schools, shadehouses, sports complexes, storage areas, substations, construction and pre-construction sites, turfgrass areas, around ornamental gardens, around ornamental trees and shrubs, power and utility sites, around commercial or industrial outbuildings, warehouse areas, bare ground, gravel yards, mulched areas, beaches, habitat restoration and management areas, uncropped farmstead areas, uncultivated non-agricultural areas, vacant lots, wastelands, shelter belts, and wildlife management areas. Natural Woodlands, including Wildlife and Habitat Management Areas, Wildlife Openings, Natural Areas (such as Wildlands and Wildlife Refuge), Campgrounds, Parks and Recreational Areas in Natural Forests, and Reforestation Treatments in Natural Forests	8	8	8
Aquatic	8	8	8
Alfalfa, Clover, and Other Forage Legumes, including: kudzu, lespedeza, lupin, sainfoin, trefoil, velvet bean, vetch, kenaf, leucaena	3.75	1.55	6
Berry and Small Fruit Crops: All cultivars, varieties and/or hybrids of Amur River grape; Aronia berry; Bayberry; Bearberry; Bilberry; Blackberry (including Andean blackberry, arctic blackberry, bingleberry, black satin berry, boysenberry, brombeere, California blackberry, Chesterberry, Cherokee blackberry, Cheyenne blackberry, common blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, evergreen blackberry, Himalayaberry, hullberry, lavacaberry, loganberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, mora, mures deronce, nectarberry, Northern dewberry, olallieberry, Orgeon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, Southern dewberry, tayberry, youngberry, zarzamora); Blueberry (highbush and lowbush); Buffaloberry; Che; Chilean guava; Chokecherry; Cloudberry; Cranberry (including highbush); Currant (black, Buffalo, red, native); Elderberry; European barberry; Gooseberry; Grape; Honeysuckle (edible); Huckleberry; Jostaberry; Juneberry (Saskatoon berry); Kiwifruit (fuzzy and hardy); Ligonberry; Maypop; Mountain pepper berries; Mulberry; Muntries; Partridgeberry; Phalsa; Pincherry; Raspberry (black, red and wild); Riberry; Salal; Schisandra berry; Sea buckthorn; Serviceberry	3.75	1.55	8

Appendix D: Endangered Species Assessment

Consistent with EPA's responsibility under the Endangered Species Act (ESA), EPA intends to complete national-level endangered species Biological Evaluations for glyphosate to assess risks to federally threatened and endangered (listed) species from registered uses of pesticides. This Biological Evaluation will be completed in accordance with the joint Interim Approaches developed to implement the recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*. The NAS report[12] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct to meet their obligations under the ESA. The methods developed as part of the joint Interim Approaches will continue to be vetted before EPA utilizes these methods broadly to meet its ESA obligations.

In November 2013, the U.S. Fish and Wildlife Service, the National Marine Fisheries Service (together, the Services), EPA, and the U.S. Department of Agriculture released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.* [13]

The ecological risk assessment supporting this Proposed Interim Registration Review for glyphosate does not contain a complete, national-level ESA analysis, including effects determinations for specific listed species or designated critical habitat. The agency intends to complete an assessment of risk to listed species prior to completing its final registration review decision for glyphosate. Final Biological Opinions for glyphosate will be developed by the Services. EPA intends to address risks to listed species identified in the Biological Opinions for glyphosate as part of its final registration review decision for glyphosate, and implement geographically-specific risk mitigation for listed species and designated critical habitats, as necessary, via *Bulletins Live! Two*. More information on *Bulletins Live! Two* is accessible at https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins.

[12] http://www.nap.edu/catalog.php?record_id=18344
[13] http://www.epa.gov/espp/2013/nas.html

Appendix E: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for glyphosate, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), glyphosate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. Glyphosate is on List 1 and the review conclusions are available in the glyphosate public docket (see EPA-HQ-OPP-2009-0361). A second list of chemicals identified for EDSP screening was published on June 14, 2013,[14] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[15] In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

[14] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[15] https://www.epa.gov/endocrine-disruption

News Releases from Headquarters › Chemical Safety and Pollution Prevention (OCSPP)

EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products

08/08/2019

Contact Information:
EPA Press Office (press@epa.gov)

WASHINGTON (Aug. 8, 2019) – EPA is issuing guidance to registrants of glyphosate to ensure clarity on labeling of the chemical on their products. EPA will no longer approve product labels claiming glyphosate is known to cause cancer – a false claim that does not meet the labeling requirements of the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA). The State of California's much criticized Proposition 65 has led to misleading labeling requirements for products, like

glyphosate, because it misinforms the public about the risks they are facing. This action will ensure consumers have correct information, and is based on EPA's comprehensive evaluation of glyphosate.

"It is irresponsible to require labels on products that are inaccurate when EPA knows the product does not pose a cancer risk. We will not allow California's flawed program to dictate federal policy," said EPA Administrator Andrew Wheeler. "It is critical that federal regulatory agencies like EPA relay to consumers accurate, scientific based information about risks that pesticides may pose to them. EPA's notification to glyphosate registrants is an important step to ensuring the information shared with the public on a federal pesticide label is correct and not misleading."

In April, EPA took the next step in the review process for glyphosate. EPA found – as it has before – that glyphosate is not a carcinogen, and there are no risks to public health when glyphosate is used in accordance with its current label. These scientific findings are consistent with the conclusions of science reviews by many other countries and other federal agencies.

On Feb. 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction stopping California from enforcing the state warning requirements involving glyphosate's carcinogenicity, in part on the basis that the required warning statement is false or misleading. The preliminary injunction has not been appealed and remains in place.

California's listing of glyphosate as a substance under Proposition 65 is based on the International Agency on the Research for Cancer (IARC) classifying it as "probably carcinogenic to humans." EPA's independent evaluation of available scientific data included a more extensive and relevant dataset than IARC considered during its evaluation of glyphosate, from which the agency concluded that glyphosate is "not likely to be carcinogenic to humans." EPA's cancer classification is consistent with many other international expert panels and regulatory authorities.

Registrants with glyphosate products currently bearing Proposition 65 warning language should submit draft amended labeling that removes this language within 90 days of the date of the letter.

For more information about EPA's comprehensive evaluation of glyphosate, visit https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073.

To read the notice to registrants, click here.

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LAST UPDATED ON AUGUST 12, 2019

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 7, 2019

Dear Registrant,

We are writing to you concerning label and labeling requirements for products that contain glyphosate.

On July 7, 2017, California listed glyphosate as a substance under Proposition 65[1], based on the International Agency for Research on Cancer's (IARC's) classification of the pesticide as "probably carcinogenic to humans." EPA disagrees with IARC's assessment of glyphosate. EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is "not likely to be carcinogenic to humans." EPA considered a more extensive dataset than IARC, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review. For more detailed information on this evaluation, please see the 2017 Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential[2]. Further, EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

On February 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction enjoining California from enforcing the state warning requirements involving the pesticide glyphosate's carcinogenicity, in part on the basis that the required warning statement is false or misleading[3].

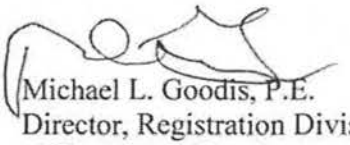
Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA. In registering pesticides, EPA must determine that the labeling complies with the requirements of FIFRA including that the product

[1] California's Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65) requires businesses to inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm. *See* California Office of Environmental Health Hazard Assessment, "Proposition 65," at https://oehha.ca.gov/proposition-65.
[2] https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073
[3] National Association of Wheat Growers, et al. v. Zeise, 309 F.Supp.3d 842 (E.D.Cal.)

not be misbranded. See FIFRA 3(c)(5)(B). Therefore, EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The warning statement must also be removed from all product labels where the only basis for the warning is glyphosate, and from any materials considered labeling under FIFRA for those products.

For any pesticide product that currently contains Proposition 65 warning language exclusively on the basis that it contains glyphosate, EPA requests the submission of draft amended labeling that removes such language within ninety (90) days of the date of this letter.

Sincerely,



Michael L. Goodis, P.E.
Director, Registration Division
Office of Pesticide Programs